

User's Guide



Thermo Scientific HyClone Single-Use Mixer


**Thermo Scientific
HyClone Single-Use
Mixer (S.U.M.)
User's Guide**

UG004 Rev 4

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NOTE: The drawings used throughout this document are representative only and may change. Please refer to your Equipment Turnover Package (ETP) for your applicable drawings. 

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Warnings and Safety



Warning: Read and understand operator's manual before using this equipment.

The Thermo Scientific HyClone Single-Use Mixer is designed to be operated under traditional pharmaceutical conditions. A general understanding of mixing systems and their operation is important prior to using the system for the first time. p

- Read and understand user's manual before operating
- Failure to do so could result in injury



Warning: Hazardous voltage inside

Disconnect power before opening. Service by trained personnel only.

Consult manual. Electrical components are designed into and required for the proper function of the Single-Use Mixer (S.U.M.). The mixer motor, motor controller, heater jacket and control panel all have electrical components. p

- Risk of electrical shock and injury



Warning: Entanglement hazard

Rotating parts can cause injury. Keep hands away from moving parts. p

Warning: Hot surface. Do not touch.

The heating jacket is designed to heat the outer vessel wall. Normal operating conditions generate heat and could create hot surfaces. p

- Hot surface inside
- Contact with surfaces may cause burns
- Do not touch while in operation



Warning: Burst Hazard

Under normal operating conditions the S.U.M. BPC chamber is under slight pressure. Normal passive venting prevents any excess of pressure building up within the chamber. Chamber pressure and inlet line pressure should be monitored for proper settings. p

- Contents under pressure
- Do not exceed 0.5 psi (0.03 bar) BPC pressure
- Do not exceed 5 psi (0.34 bar) inlet pressure
- Assure vent filter is properly positioned and working properly

Protective Earthing

Protective earthing for the Single-Use Mixer hardware system and controller is provided through the ground terminal of the plug providing power. Source power to the controller must provide protective earthing to this terminal in order to minimize the hazard of a possible shock in the occurrence of a fault condition.

Environmental Conditions

- Operating: 17°C to 27°C; 20% to 80% relative humidity, non-condensing
- Storage: -25°C to 65°C
- Installation category II (over voltage) in accordance with IEC 664
- Altitude Limit: 2,000 meters

Electrical Connections

Power to the Single-Use Mixer should be supplied by a non-GFCI 15 amp circuit.

Ground faults occur when current is leaking somewhere, in effect, electricity is escaping to the ground. Electrocution can occur when the human body serves as the path for the leakage to the ground. A Ground Fault Circuit Interrupter (GFCI) senses the current flowing to the ground and switches off the power (trips the GFCI) in a fraction of a second at currents well below those that are considered dangerous. Due to the sensitivity of GFCIs to electrical leakage (a few mA), it is recommended that the Single-Use Mixer NOT be plugged into a GFCI outlet.

Water Jacket Vessel Information

The Water Jacket S.U.M. has been designed to be operated with water as the heat transfer medium with temperatures not exceeding 140°F (60°C) under less than 150 psi (1 MPa) operating pressure. **NOTE:** The S.U.M. BPC operating limits for temperature are 5 to 40°C and an internal pressure of less than 0.5 psi. This jacket is not classified as a pressure vessel and is not required to be registered, inspected and stamped with the Code U symbol per section U-1(c)2(f) of the ASME Boiler and Pressure Vessel Code operating with water as the heat transfer medium, temperature not exceeding 210°F (99°C) under less than 300 psi (2 MPa). In Europe, to conform to the Pressure Equipment Directive 97/23/EC (PED), all S.U.M. jacketed systems should be operated at 75 psi or less. However, if operating conditions require usage outside of the above recommended parameters, a stamped jacket can be obtained for an additional fee.

Section 1 Single-Use Mixer (S.U.M.) Overview

This section covers the following information:

- 1.1 Introduction
- 1.2 Hardware Characteristics
- 1.3 End-User Supplied Components
- 1.4 BioProcess Container Characteristics
- 1.5 Additional/Optional System Components
- 1.6 Initial Installation Instructions
- 1.7 Installation and Setup
- 1.8 Operating Instructions

1.1 Introduction

The Thermo Scientific HyClone Single-Use Mixer (S.U.M.) offers a single-use alternative for traditional stirred tank mixing. It is based on the same mixing principle as the Thermo Scientific HyClone Single-Use Bioreactor (S.U.B.). Both systems use an impeller linked to an overhead mixing motor via a sealed bearing assembly which allows the impeller to turn while maintaining the integrity of the system.

The S.U.M. is intended for powder-liquid and liquid-liquid closed system mixing with sterile single-use contact surfaces.

Each S.U.M. system consists of:

1. Stainless Steel Reusable Hardware System – providing support, mobility, mixing motor and control system. Available options include:
 - Integrated hardware with tank and mixing motor on the same skid (Figure 1.1).
 - Docking Station System with the mixing motor mounted on a separate docking frame designed to link to a range of separate tanks (Figure 1.2).
 - Tanks with and without heating/cooling jackets (Figure 1.3).
2. Single-Use BioProcess Container (BPC) – providing sterile, ready-to-use single-use contact surfaces including impeller, sealed bearing assembly and tubing for liquid transfer. Available options include:
 - Open top liner for media/buffer preparation.
 - Closed BPCs with powder port designed to integrate with the HyClone Powdertainer to provide ergonomic and contained media/buffer preparation.
 - Closed BPCs with monitoring probe capability.
 - Closed BPCs for liquid-liquid mixing of critical sterile solutions.

Further information on the S.U.M. product offering can be found in Section 3.

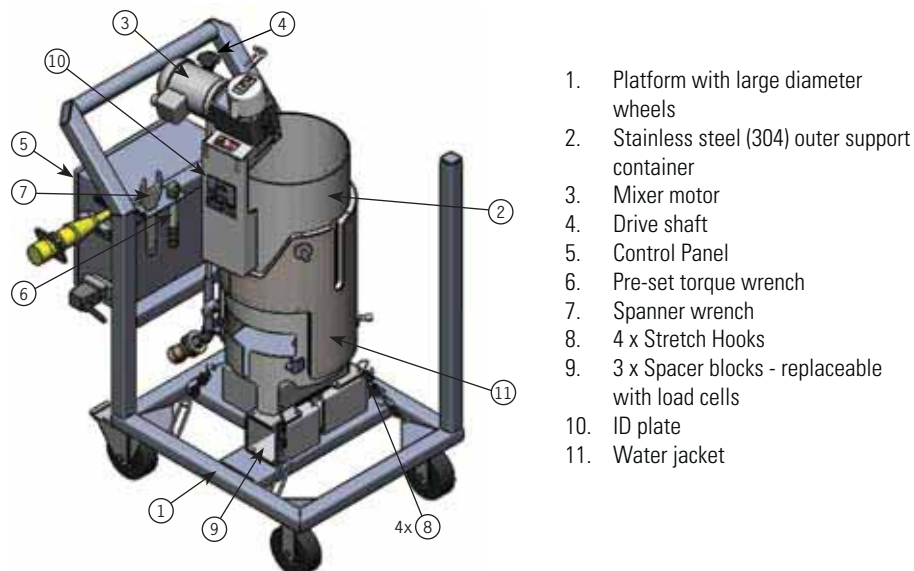


Figure 1.1 50 L Jacketed S.U.M.

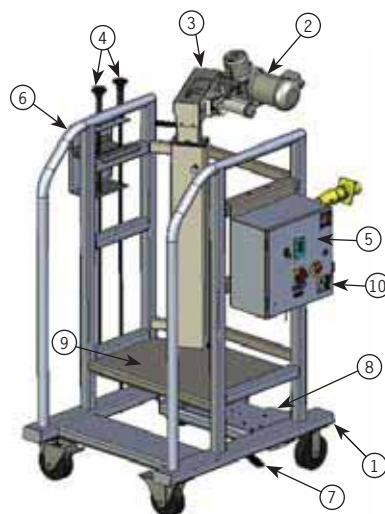


Figure 1.2 Docking Station Frame

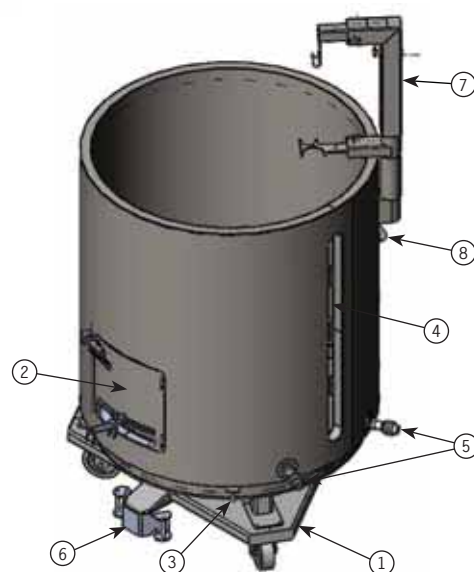


Figure 1.3 1000 L Jacketed Docking Tank

This user's guide covers the setup, operation, maintenance and troubleshooting of all S.U.M. products with stainless steel hardware systems in the following volumes – 50, 100, 200, 500, 1000 and 2000 L.

1.2 Hardware Characteristics

System Features

The Single-Use Mixer (S.U.M.) is designed for system mobility and easy disposable integration while utilizing a straightforward operator interface. **NOTE:** Systems larger than 1000 L are not mobile. Hardware drawings and specification tables for volume can be found in Section 3. The following sections describe the hardware components of the S.U.M.

Agitation

Stirring speed is adjusted by using the keypad interface on the control panel. The agitation control interface utilizes a digital display to indicate stirring speed in units of revolution per minute (RPM). Power is supplied to the motor by a two position power switch. The up and down arrows on the agitation keypad adjust the stirring speed.

Mixer Control System

The S.U.M. control system manages the process parameters of agitation only. Parameters of pH and temperature control must be managed by an external controller supplied by the end-user.

Temperature (Water Jacket)

The Water Jacket S.U.M. is designed to be operated with water as the heat transfer medium with a temperature range of 2°C to 60°C. The process temperature can be monitored by means of an optional RTD (Pt-100) inserted into the thermo-well of a probe port equipped S.U.M. BPC. Water Jacket system temperature control is maintained through a temperature control unit (TCU) supplied by the end-user.

Load Cells

Load cells are optional on all stainless steel S.U.M. hardware except for docking tanks. Load cell kits can be installed at the factory or can be added later by a certified service technician. The load cell kit comes with three load cells, summing block, wiring and display with a choice of several data interfaces.

Load cells arrive uncalibrated; it is recommended the load cell manufacturer or a qualified technician calibrate these systems on site.

1.3 End-User Supplied Components

pH Probes

The following table shows the length and diameter requirements for sensor integration into the S.U.M. These requirements are based on the necessary insertion depth of the probe when used with the probe ports.

Recommended pH Probes					
Probe Lengths (from o-ring to tip) Must Not Exceed 235 mm				O-ring to probe tip	
				Print/Lit.	Actual
Probe	Part Number	Diameter (mm)	Thread Type	Length (mm)	Length (mm)
AppliSens pH	Z001023510, Z001023511	12	13.5 PG	235	235
Mettler Toledo pH	405-DPAS-SC-K8S/225, PN 104054481IG	12	13.5 PG	195	219
Broadley-James pH	F-635-B225-DH	12	13.5 PG	225	219
Finesse pH	PHS-EFP-K8-225	12	13.5 PG	225	220
NOTE: Consult probe manufacturer for appropriate probe cable connection and part number. p					

Table 1.1 Manufacturers and models of S.U.M. compatible pH probes.

Controllers

Many controllers can be adapted for use with the S.U.M. Table 1.2 lists several controllers that will work well when controlling pH. Users seeking advanced control functionality and data logging capabilities for parameters of pH, temperature and agitation can determine their own preferred approach in order to interface these parameters with a single controller. Please refer to the Equipment Turnover Package (ETP) supplied with each hardware system for electrical schematics. Discussions regarding the integration of specific control systems for advanced control functionality should be directed though technical support staff for Thermo Scientific HyClone products and the associated controller manufacturer.

Controller Manufacturer	Model
Applikon	ADI "10 Series" Model 1010, Part Number Z510100010 Model 1025, Part Number Z310250010
Applikon	i-Control , ez-Controller
Bellco	500 Series
Broadley-James	BioNet Series
Emerson	DeltaV
New Brunswick Scientific	CelliGen Series
New Brunswick Scientific	BioFlo Series
Sartorius BBI	BIOSTAT Series
Siemens	SIMATIC "PCS" Series
Siemens	TELEPERM Series
Finesse	TruViu

Table 1.2 Manufacturers and models of S.U.M. compatible controllers.

1.4 BioProcess Container Characteristics

Single-Use Mixer BPC Features

The Single-Use Mixer BPC (or alternatively the liner) contains the mixing process. The BPC chamber is manufactured from CX5-14 film and the liner from CX3-9 film. Both are co-extruded structures specifically designed for biopharmaceutical process usage. All materials are qualified for a range of physical, mechanical, biological and chemical compatibility requirements. The mixer BPC is pre-sterilized using validated gamma irradiated processes. Two standard BPC configurations are available for powder-liquid applications and liquid-liquid applications each available with or without probe ports. A liner is also available with a separate impeller or sheath system for open-top mixing.

Operating Pressure

The S.U.M. BPC is not rated as a pressure vessel (gas pressure should not exceed < 0.5 psi within the BPC). The mixer BPC should not be allowed to become tight during inflation. Conditions of over pressure may result in BPC damage or personal injury. Custom BPCs can be ordered with an optional disposable pressure transducer for monitoring the pressure within the S.U.M. via a monitoring system (not supplied).

Working Volume

Each S.U.M. is designed for a working volume range. The minimum working volume and the rated working volume are listed in the specification tables provided in Section 3. Actual working volumes should not exceed the indicated rated working volumes. However, if necessary, the BPC can accommodate a slight volume overage (68 L for 50 L S.U.M.; 220 L for 200 L S.U.M.; 550 L for 500 L S.U.M.; 1100 L for 1000 L S.U.M.; 2100 L for 2000 L S.U.M.) Working volumes less than the stated minimums listed can result in damage to the S.U.M. BPC and hardware malfunction.

Draining

The S.U.M. is equipped with a bottom drain line that allows for liquid harvest by means of peristaltic pump. Connection of the bottom drain line can be accomplished by use of the provided 1/2" (12.7 mm) quick connect. Manipulation of the S.U.M. BPC as the last few liters of fluid are removed can minimize liquid hold-up.

Multiple aseptic connection options exist for S.U.M. users. The standard BPC includes tubing welder sections, quick connects for use under a laminar flow hood and steamable sanitary connections (liquid-liquid BPC). The S.U.M. BPC is designed with various lengths and dimensions

of thermoplastic tubing for the purpose of addition and dispensing from the S.U.M. BPC. Refer to Ordering Information in Section 4 for custom-end treatment options.

Aseptic Connections

During operation of the S.U.M., samples may need to be taken for monitoring of various parameters established by the user (pH, spectrophotometric analysis, osmolality, etc). Samples can be taken from the S.U.M. in various ways dependent upon the BPC configuration. Samples are easily taken by utilizing the recirculation loop and the SmartSite port on all standard BPC configurations. In full volume applications where the recirculation loop is not being utilized, samples can be taken directly through the powder port, using one of the line sets on the top of the BPC, or through the drain line.

Sampling

For BPC configurations that utilize probe ports, the S.U.M. can also be equipped with a small volume sample port that is part of the BPC thermowell. This small diameter silicone dip tube of 6" length (15.24 cm) allows low void volume samples to be taken. The dip tube is supplied with an aseptic luer lock connector (SmartSite) that allows for direct sampling or attachment of various sampling manifolds by use of standard luer lock connection. Alternatively, manifolds can be welded onto the C-Flex sample line by a tubing welder.

BPC drawings and standard configuration tables specific to volume can be found in Section 3.

1.5 Additional/ Optional System Components

Probe Integration

The probe assembly is an innovative disposable design to package user supplied pH probes for sterilization (if applicable) and to aseptically connect them to the S.U.M. BPC. The probe assembly (Figure 1.4) includes the following components:

1. Molded bellows cover
2. Threaded probe adaptor
3. Pall Kleenpak Connector (KPCHT Series - high temperature)
4. Cable ties

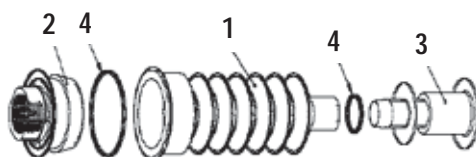


Figure 1.4 Probe Assembly

Required and Optional Accessories

To assist in the operation of the Single-Use Mixer the following additional accessories are available (see Section 4 for ordering information)

Powder-Liquid Configurations

- Thermo Scientific HyClone Powdertainer Hanger and holding arm
Optional for hanging and positioning of powder bag

All Configurations with Probe Ports

- Heavy duty tubing clamps
Required (one per Kleenpak port used)
- Probe shelf and probe clips
Shelf and standard probe clips required for use with probe assemblies except for docking tanks which use hanging probe clips with the need for a shelf
- Stainless steel autoclave tray for probe kits (aseptic applications)
Required for probe sterilization (minimum of one required) - The support tray provides an inclined fixture for two probes during autoclaving to minimize stress on the probes and to prevent collapse of the silicone bellows.
- RTD
Optional for temperature monitoring
- S.U.M. thermo-well or sample port (for RTD calibration and validation)
Optional

Open-Top Mixing Configurations

- A reusable bearing port (hub) is used for all open-top mixing applications. The quick connect style is used for all S.U.M. sizes except for the 2000 L, which uses a tri-clamp style bearing port.

Options for All Configurations

- Load cells
Optional—Consists of three load cells, summing block, wiring and display with choice of several data interfaces.
- Hatch or Doors
Optional—Easily removed from their hinges and replaced with alternative cutouts and openings in the door or hatch.
- Drain plate
Optional—Alternative designs may be utilized to facilitate multiple drain configurations.

1.6 Initial Installation Instructions

Hardware Shipment and Setup

The Single-Use Mixer hardware is shipped directly from the manufacturer and will arrive crated. Be sure to follow the unpacking instructions provided and **retain all packaging materials for possible future use.**

Hardware Uncrating

The S.U.M. hardware should arrive with the following items:

- Outer support container (platform, tank, probe door plates (2) and control panel)
- Powder arm assembly (optional)
- Drive shaft mounted in the drive shaft holder
- Torque and spanner wrenches
- Equipment Turnover Package – located on CD provided with hardware.

S.U.M. Docking Station should arrive with the following items:

- Docking Frame
- Control Panel
- Motor and mount
- Drive shafts (2)
- Torque and spanner wrenches
- Accessory tray
- Equipment Turnover Package – located on CD provided with hardware

S.U.M. Docking Station Tank should arrive with the following items:

- Outer support container (platform, tank, probe door plate)
- Powder Arm Assembly (optional)
- Hanging probe clips

To unpack hardware:

1. Remove side wall(s)
2. Remove the tie-down straps
3. Remove any blocks on crate floor
4. Remove S.U.M. **carefully** either using a forklift or by manually lifting the bottom of the cart frame and not the casters
5. Ensure no damage occurred during shipping

Contact your sales representative immediately if damage has occurred.

Note: When the docking station system and 2000 L S.U.M. hardware are removed from their crates they require some partial assembly. Please use the applicable instructions below:

Docking Station Assembly

1. Attach motor assembly (about 30 lbs) to top rail and mast assembly (Figure 1.5).
2. Insert 1/4"-20 set screw, p/n 92311A540, in top rail with 1/8" hex key (Figure 1.6).
3. Attach top cover, p/n 19536, to mast assembly by inserting six 10-24 button head cap screws, p/n 92949A242 with 1/8" hex key (Figure 1.7).



Figure 1.5 Motor assembly to top rail



Figure 1.6 Insert set screws



Figure 1.7 Attach top cover

4. The tooling bracket and electrical panel are shipped bolted to the inside of the Docking Station frame. Simply use the same bolts to fasten the components to the outside of the frame to prepare the Docking Station for use.

2000 L S.U.M. Assembly

Motor to Tank Assembly:

Safe assembly will require two personnel.

1. Remove motor with pre-attached mounting piece from packaging.
2. While one person holds the motor in place, the second person inserts the (4) $\frac{3}{8}$ " x 6.25" bolts through the front of the motor block portion of the motor support arm that is part of the tank (do not fully tighten bolts yet).
3. While the first person supports the motor, the second inserts a $\frac{3}{8}$ " x 1" bolt through the right and one through the left side of the motor block into the motor mounting piece. Tighten all bolts.

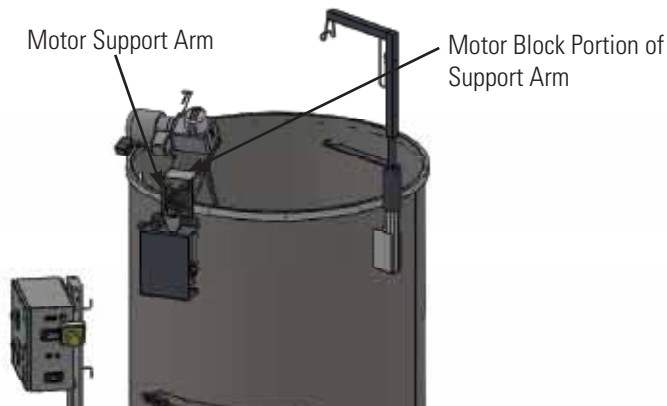


Figure 1.8 Electrical Panel Support Arm Assembly

Electrical Panel Support Arm Mounting:

Safe assembly will require two personnel.

1. Remove electrical panel support arm from packaging.
2. Attach support arm to the frame directly under motor with (2) $\frac{3}{4}$ " x 1" hex head bolts and (2) $\frac{3}{4}$ " SST flat washers. Do not tighten until both bolts have been installed (Figure 1.9).



Figure 1.9 Electrical Panel Support Arm Assembly

2000 L S.U.M. Assembly (continued)

Electrical Panel Mounting:

Safe assembly will require two personnel. Electrical panel support arm must be installed first.

1. Remove electrical panel from packaging.
2. Using a flat headed screwdriver, open panel door.
3. One person holds electrical panel with holes aligned with the hole pattern on the support bracket of the electrical panel support arm.
4. Second person inserts from the inside of the electrical panel (4) 3/8" x 1" button head bolts with (4) 3/8" SST flat washers (Figure 1.10).
5. On the back of the support bracket the second person adds (4) 3/8" SST lock washers and (4) 3/8" SST acorn nuts (Figure 1.11).
6. Tighten all bolts and nuts.



Figure 1.10 Panel to support arm assembly



Figure 1.11 Panel to support arm assembly

Site Preparation

Electrical Connections

The S.U.M. hardware cannot be used on circuits equipped with GFCI circuit protection because of the potential for nuisance tripping. The electrical plug on the S.U.M. is a connector offering a secure ground. These connectors meet the electrical safety codes for portable equipment are International Electrical Code (IEC) rated (meet IEC standard 60309). This plug serves to provide electrical ground prior to power connection. The supplied electrical receptacle should be hardwired into the facility by a qualified electrical technician; for US installations the receptacle will require the use of an adapter mounting plate (supplied) which will fit into a 'two gang' box. For additional information on the adapter mounting plate, please see the ETP. Alternatively, the system can be hardwired directly into the facility.

Outer Support Container Preparation

Each outer support container is shipped directly from the manufacturer and arrives with various safety mechanisms in place. Please follow the guidelines below to set up the Single-Use Mixer upon arrival.



Warning: Any procedures that require the control box to be open should be performed with the main electrical disconnect in the locked out position and all power sources removed from the control box. For operator safety, secure the location of the S.U.M. outer support container by disabling the swivel casters before servicing. p

1. Before beginning, refer to electrical schematics included with the ETP which is located on CD provided with hardware.
2. Using a flat headed screwdriver, open the control box. Verify position of the three-way motor controller switch—it should be in the middle position (Figure 1.12).
3. Close the control box and lock the panel using a screwdriver before continuing.
4. For S.U.M. hardware units purchased with factory installed load cells, the load cells are shipped in the locked position (threaded up) for equipment protection. Refer to Load Cell Preparation instructions included.
5. At this point, the S.U.M. hardware is ready for operation.

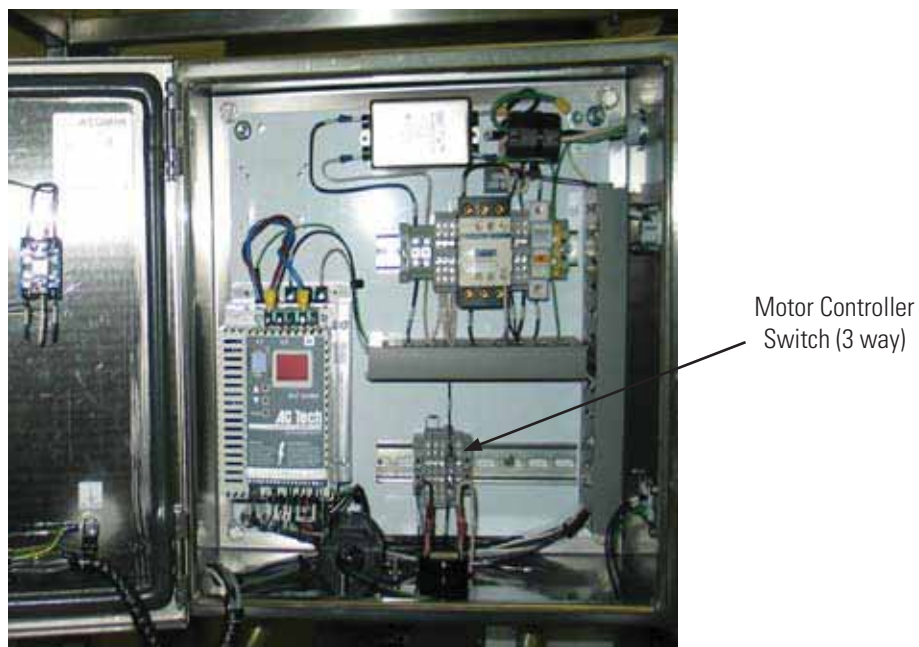


Figure 1.12 Control Box for S.U.M.

Load Cell Preparation

For S.U.M. hardware units purchased with factory installed load cells, the load cells are shipped in the locked position (centering washer and nut are threaded up) for equipment protection (Figure 1.13). To unlock the load cells, loosen the centering washer and nut ($5/8$ " nut) until the nut is threaded down on the hold-down bolt about half way. Next, loosen the jam nut on the base plate until the jam nut and centering washer and nut meet. Tighten both nuts together. Using an open-end wrench, loosen the hold down bolt to provide clearance below and above the cutout in the top plate (Figure 1.14). The clearance around (above and below) this nut should be from $1/8$ " to $3/16$ ". Once the proper clearance has been achieved, retighten the jam nut.



Figure 1.13

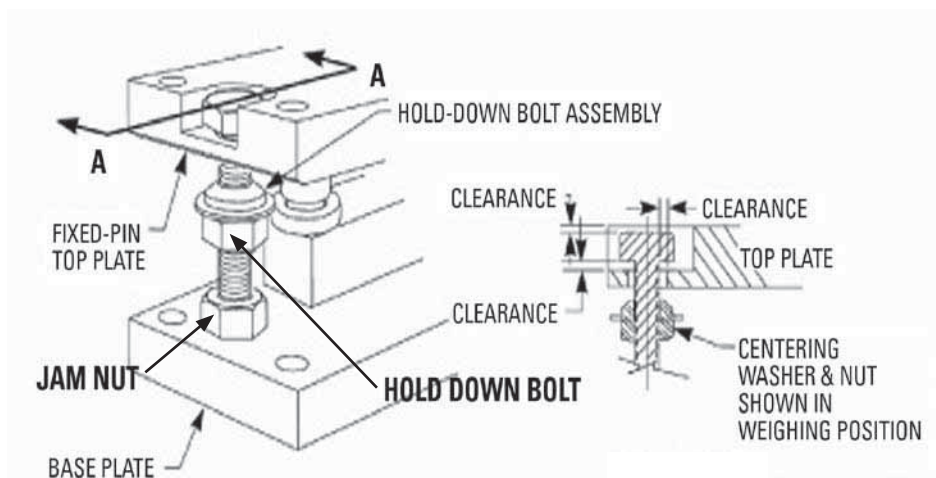


Figure 1.14 Unlocking Load Cells

Additional Items for Installation

Attach the optional probe shelf across the lower probe access cutout by inserting the two tabs into the slots (Figure 1.15) and hand tightening the knobs (Figure 1.16). **Note:** Docking tanks do not utilize a probe shelf.



Figure 1.15



Figure 1.16

1.7 Installation and Setup

Outer Support Container Preparation

All manual movements of the S.U.M. hardware should be over smooth surfaces with the S.U.M. empty and disconnected from all power and feed sources. **Refer to the appropriate subsection within Section 3 of this user's guide for graphics illustrating the control panel interface for the appropriate hardware.**

1. Verify facility electrical supplies are sufficient to support the power requirements of the S.U.M. and ancillary components such as controllers or pumps.
2. Locate the outer support container in the area for operation.
3. If monitoring the volume, the unit may be located on a scale if load cells are not utilized. Other applications may measure all liquids going in and coming out.
4. Engage the caster brakes on the wheels of the outer support container and/or Docking Station.
5. Verify the location of the pH controllers (if used) and assure cable/tubing lengths are satisfactory.



WARNING: ELECTRICAL SHOCK. p

6. Verify the main power is off and the emergency stop is pulled out.

NOTE: THE EMERGENCY STOP DISCONNECTS ALL POWER TO THE SYSTEM. AN ALARM BUZZER WILL SOUND WHEN THE EMERGENCY STOP IS ACTIVATED. p

7. Verify the main motor power switch is in the off position.
8. Connect all electrical plugs to facility power. Refer to hardware/ electrical labels and schematics to ensure proper electrical voltage is connected to the S.U.M. The main power switch can now be turned on.

9. If applicable, connect water inlet and outlet lines from temperature control unit quick connects to the jacket (Figure 1.17). The inlet is typically on the left side if facing the connectors.



Figure 1.17 Water Jacket Connection

10. See Section 2.7 for hardware modifications required for use in open top mixing applications.
11. Install powder arm mast by placing over the indicated post (optional).

1.8 Operating Information

BPC Preparation and Setup

The following section outlines the installation and setup of the S.U.M. BioProcess Container and hardware. Please become familiar with the layout of the BPC and the hardware before beginning installation of the bag. For reference, the front of the bag is designated as the panel containing the bearing port; this should face the bearing port receiver and motor as the bag is loaded. In addition, confirm the correct volume BPC is being used for the corresponding volume outer support container.

BPC Handling Instructions

Do not use scissors or any sharp objects when opening outer polybags. When placing bags in containers, do not drag bag over corners or sharp objects. Do not lift the bag by the corners or top seams. Allow bag to fill to capacity. After filling, disconnect bag from fill line. Carefully coil tubing on top of bag to prevent puncturing bag with cable ties or clamps. Use cushioning between tubing and bag in storage and transport.

Working Volume

Each S.U.M. is designed for a working volume range. The minimum working volume and the rated working volume are listed in Section 3. In normal operation, the actual working volumes should not exceed the indicated rated working volumes.

Liquid Transfer

The S.U.M. BPC is designed with thermoplastic tubing, quick connects and tri-clamps for the purposes of addition and dispensing from the BPC. For liquid-liquid applications, a sterile environment can be maintained as long as all connections are made in an aseptic manner. To maintain sterility of the mixing system, connection of additional lines (quick connects and tri-clamp) should be made under a laminar flow hood or with a sterile tubing welder. Consult the following table for tubing welder die recommendations.

Recommended Tubing Welders for Aseptic Connections			
Brand	Model/die set	Tubing Size OD - ID	Tubing Material
Wave	STF-IRc (5/8" [15.88 mm])	3/8-5/8" (9.53-15.88 mm)	C-Flex
Wave	STF-IRc (3/4" [19.05 mm])	1/2-3/4" (12.7-19.05 mm)	C-Flex

Table 1.3 Recommended Tubing Welders

Dispensing

The agitator should not be operated at volumes less than the stated minimum volume. The S.U.M. is equipped with a drain line that allows for liquid removal by means of peristaltic pump. The drain is located at the bottom of the S.U.M. BPC allowing for minimal hold up volumes. Connection of the bottom drain line can be accomplished by use of the provided 1/2" (12.7 mm) quick connect. **Turn off agitation during draining when approaching the minimum working volume.**

Hardware Operating Information

Temperature Control (Water Jacket Systems)

Connection to an external temperature control unit (TCU) is made via the large quick connect couplings located on the vessel jacket. Ensure the inlet or outlet ports are connected properly; improper installation may result in poor heating and cooling performance. Temperature setpoints are controlled by the TCU. Refer to the TCU manufacturer's guidelines for setup and operating instructions.

Drive Shaft Rotation

Verify rotation of the drive shaft is counterclockwise when viewed from the top looking down. The S.U.M. is designed to mix in this direction only.

Load Cells and Weighing Systems

Digital display weighing scales can be sourced from manufacturers such as Mettler-Toledo. Bench top scales are commonly used to measure the amount of bulk source media stored in a smaller volume BPC as it is transferred by peristaltic pump into the S.U.M. Floor scales can be used to measure the fluid content within the S.U.M. This is accomplished by rolling the S.U.M. onto the scale platform. If using a floor scale for the Docking Station tanks, the system must be elevated by the same height to ensure proper orientation of the mixer. See Section 3 for skid dimensions and weights when selecting a scale system.

An option available for the S.U.M. is a load cell kit for weight and volume measurement. Load cell kits can be installed at the factory or can be added later by a certified service technician. The load cell kit comes with three load cells, summing block, wiring and display with a choice of several interfaces. For more information, see Section 4 for ordering information.

Instructions for Protective Earthing

Protective earthing for the Single-Use Mixer hardware system and controller is provided through the ground terminal of the plug providing power. Source power to the controller must provide protective earthing to this terminal in order to minimize the hazard of a possible shock in the occurrence of a fault condition.

Replaceable Fuses

Electrical components of the Single-Use Mixer are equipped with circuit protection. The variable frequency drive used to power the mixer motor is protected by the use of quick blow fuses. In the case of an electrical fault condition, these safety devices are designed to protect the user from electrical shock and prevent electrical system components from being damaged. Fuses can be replaced or breakers reset once the fault condition is resolved. See Table 1.4 for information on fuses.

Recommendations for fuse replacement			
System	Description/ Fuse Rating	Fuse Brand	Part Number
S.U.M. (All sizes) (120-240 V)	Fuse: 15A midget, quick blow	Ferraz Shawmut	OTM15

Table 1.4 Recommendations for fuse replacement

Routine Maintenance

Environmental conditions, operating parameters and the ability of the user to adhere to standard operating procedures as outlined in this user's guide can have significant impact upon the useful life of the S.U.M. hardware system. The following guidelines are based upon standard operating conditions as outlined in this user's guide.

High wear items such as bearings, seals, o-rings and sterilization valves common to conventional systems have been purposefully considered in the design of the disposable construction of the S.U.M. This creates a mixing system that is inherently robust and requires low levels of routine maintenance. Taking time between mixing batches to clean the exterior of the S.U.M. is certain to improve the appearance and overall longevity of the hardware system. The drive motor is an industrial grade induction motor with a permanently sealed and lubricated gear box. The drive shaft is constructed to wear slightly with use and should be visually inspected after each run. Visual inspection of wear components and following the guidelines listed will be sufficient to ensure years of dependable service. For information on replacement parts refer to Section 4.

Preventive Maintenance Schedule

It is recommended to replace the drive shaft assembly after 1 year of service or refer to the following wear specifications:

- See Table 1.5 for minimum drive shaft head hex diameters. Diameters are measured at widest location across the points. Replace worn shaft head assembly when drive hex diameter at widest location measures equal to or less across the points (Figure 1.19).

S.U.M. System	Minimum Hex Diameter
50, 200, 500 and 1000 L	0.566" [14.4 mm]
2000 L	0.820" (20.8 mm)

Table 1.5 Shaft head dimensions

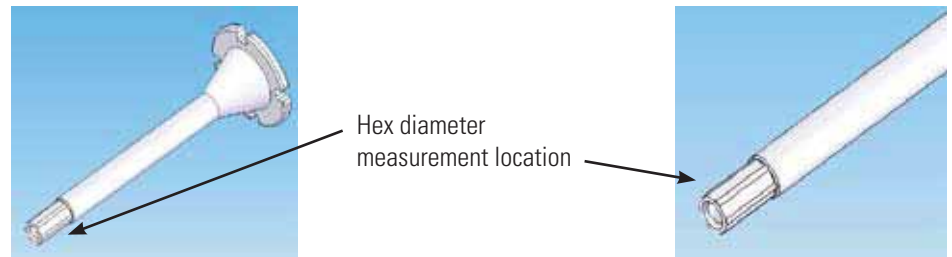


Figure 1.19 Shaft head assembly

- Lightly coat drive cap threads with food-grade anti-seize if cap becomes difficult to turn.
- Replace drive motor after twelve months of service.

Section 2 Operating Information

This section covers the following:

- 2.1 Calibration Procedures
- 2.2 Docking Station Preparation
- 2.3 S.U.M. BPC Loading Instructions
- 2.4 Probe Assembly
- 2.5 Operating Instructions
- 2.6 Pall Kleenpak Connector Instructions
- 2.7 General Mixing Protocols
- 2.8 Open-Top Mixing Hardware Installation

2.1 Calibration Procedures

Mixer Speed Calibration

To verify the calibration of the mixer speed, use a calibrated tachometer. Expect accuracy of +/- 1 rpm. Speed scaling can be modified if the calibration needs to be adjusted. Please refer to Section 3 for details.

RTD Calibration

To verify the calibration of the temperature controller/RTD, use a silicone thermo-well, the existing 1/8" OD RTD and a user supplied calibrated temperature bath.

Load Cell Calibration (when present)

Load cells arrive **uncalibrated**; it is recommended the load cell manufacturer or a qualified technician calibrate these systems on site. Expect accuracy of +/- 0.5 kg. Basic load cell default parameters are listed in the electrical schematic included with the ETP.

2.2 Docking Station Preparation

For Docking Station Only

- Set the three axis positions for the drive system according to the desired tank volume (200, 500, or 1000 L). **NOTE:** All movements have preset detents for each discrete volume size.
- Adjust the motor height by pulling the spring plunger knob (A Figure 2.1) on the motor mast assembly and positioning to the correct tank volume. **NOTE:** There are also setting to accommodate floor scale use.
- Release the spring plunger knob to lock in the mast. **NOTE:** The mast support has a built in mechanical assist such that little force is required to move the motor mast assembly.
- Release the horizontal motor lock arm by pulling the spring plunger knob (C Figure 2.1) and slide the motor assembly to the correct tank volume
- Engage the horizontal motor lock arm.

- Release the rotation motor lock (É Figure 2.1) and rotate the motor to the correct tank volume.
- Engage the rotational motor lock.
- Engage the docking station to the tank by aligning the receiving mechanism (Å Figure 2.2) to the front of the docking station. Units will self align as the two units are connected. Lock in place using the docking lock handle (Ç Figure 2.2). Ensure that the units are engaged by reversing the movement to see if the units separate.
- Lock all available locking casters with the tank and/or Docking Station. **NOTE:** The operator will need to make engagement adjustments if a non-recommended floor scale is utilized.
- Alternatively, a bag can be pre-loaded in a docking tank prior to docking by using the Powdertainer Hanger port arm (Figure 2.3) to hold in place the bearing port. The shaft cannot be inserted until the tank is docked to the station and the bearing hub is secured into the bearing port receiver.

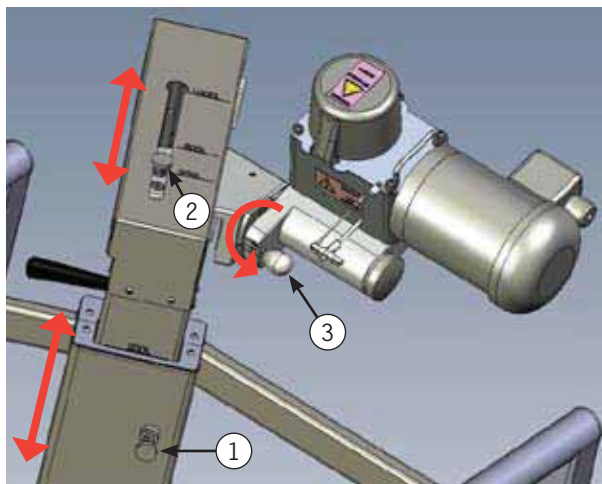


Figure 2.1

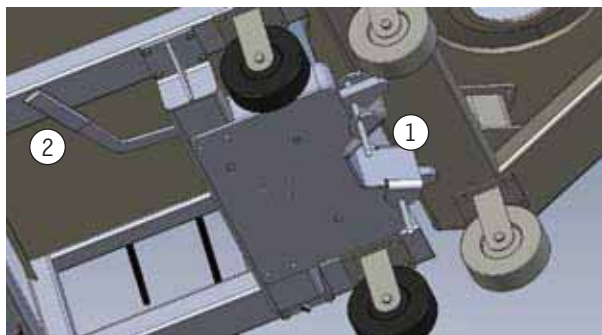


Figure 2.2

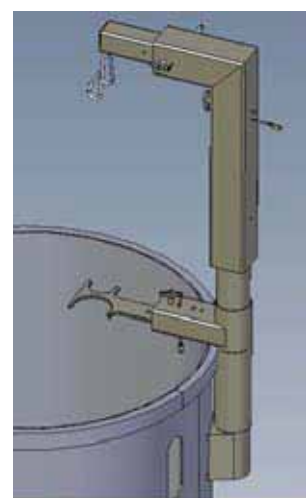


Figure 2.3

2.3 S.U.M. BPC Loading Instructions

The following steps outline loading of the BPC into the outer support container. **NOTE:** Adherence to these procedures is critical to the successful operation of the S.U.M. For larger S.U.M. models (greater than or equal to 500 L) we recommend two operators are available for BPC loading and they have access to a ladder or other means of elevation.

1. Remove the probe door plates or unlatch the door from the outer support container for ease in loading of the BPC into the container (Figures 2.4, 2.5). Alternatively, for the front door of docking tanks already docked into the station simply use the larger probe window for access in bag loading.
2. Remove irradiated mixer BPC from protective double polybags (Figure 2.5). Visually verify the configuration of the bag (powder-liquid BPC or liquid-liquid BPC) and close all line set clamps. **NOTE:** Make sure the drain line clamp is located as close as possible to the BPC port and is completely closed.

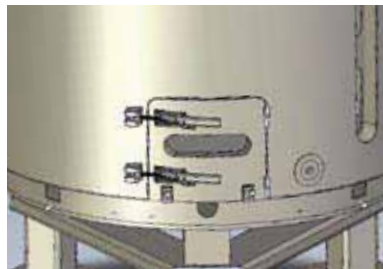


Figure 2.4



Figure 2.5

3. Orient S.U.M. BPC with bearing port up and toward motor drive with Kleenpak Connector probe ports facing bottom access cut-out if applicable. Load S.U.M. BPC from the top into the outer support container
4. Route the drain line through the bottom plate where applicable (Figure 2.6). The bottom plate may be removed to facilitate loading this lower line set. Where applicable, route the drain line through the side access panel and slot in tank bottom (Figures 2.7, 2.8).



Figure 2.6



Figure 2.7



Figure 2.8

5. If applicable, verify all port clamps are closed on port connector lines and are located as close as possible to the body of the S.U.M. BPC (Figure 2.9).



Figure 2.9

NOTE: Verify the two black bumpers located in the motor mount block are present (Figure 2.10). p



Figure 2.10 Location of black bumpers

6. Place the bearing port into bearing port receiver, close door and clamp (Figures 2.11, 2.12).



Figure 2.11



Figure 2.12

7. Use the four bottom cut-outs located at the base of the support container as a reference to align positioning tabs on S.U.M. BPC (Figure 2.13).



Figure 2.13



Figure 2.14

8. Attach platform stretch hooks to each of the four bottom corners of the BPC (Figures 2.13, 2.14). For the 2000 L and Docking S.U.M. units, hatches are provided in the tanks to facilitate attachment of the positioning tabs to the retention pins (Figure 2.15).



Figure 2.15

9. Once the bag is fully seated, check the drain line remains fully extended through the bottom port and the bearing port on the BPC is in the proper position (facing the receiver port) before proceeding to the next step. To keep the drain line from contacting the floor, the line can be guided through one of the bars located on the base of the outer support container.
10. Once the bearing port is engaged, make sure the film is not being pulled tight around the bearing port. The area of the bag affected is located on the front BPC panel, below the bearing port (Figures 2.16, 2.17). To ensure proper insertion of the drive shaft and to reduce tension on the bearing port, pull up slightly on the front panel of the BPC to provide excess film in the affected area.

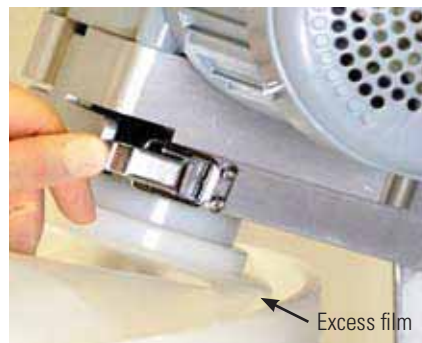


Figure 2.16 Proper Loading



Figure 2.17 Improper Loading

Recirculation Line Setup

11. Replace the probe door plate on the side opposite the probe belt. If not utilizing the probe ports, replace both probe door plates (except on the 2000 L and Docking Station Tank).
12. If applicable, align row of side ports within access window.
13. Set up recirculation or sampling loop if desired. To create the recirculation loop, run the drain line through a peristaltic pump and connect it to the recirculation or sampling line set. For sterile applications, this connection must be made under a laminar flow hood or by utilizing a sterile tubing welder. Make sure the clamps on the recirculation line are closed before filling the BPC with liquid.
14. Drain line should be fully extended through the front cut out, bottom slot or bottom plate of the outer support container.
15. Drape the recirculation or sampling line over the outside of the support container.
16. Run the drain line through the head of a peristaltic pump and locate the pump head close to the drain outlet (Figure 2.18).



Figure 2.18

17. For non-sterile applications join the quick connects of the recirculation or sampling line and the drain line to form the recirculation loop. To make this connection, open the tamper evident polybag covering the quick connects on the recirculation or sampling and drain lines (Figure 2.19). Remove the caps from the quick connects. Line up the recirculation and drain quick connects and make the connection (Figure 2.20).

NOTE: For sterile applications this connection must be made under a laminar flow hood or by utilizing a sterile tubing welder.



Figure 2.19



Figure 2.20

18. When ready to utilize the recirculation loop, open all clamps on both line sets. See Figure 2.21 for a completed recirculation loop.



Figure 2.21 Completed recirculation line setup

19. Before beginning liquid fill, verify all parts of the mixer (drive shaft, BPC, probe door plates (2), probe shelf with fingers and tools) are located on the outer support container before taring the skid on the scale.
20. Tare the skid on the scale with the BPC installed. Refer to internal formulation procedures before proceeding.

NOTE: During the manufacturing process, a slight vacuum forms inside the BPC causing the panel surfaces to cling to each other and the impeller assembly. Before the drive shaft can be inserted this vacuum must be released either by opening the tri-clamp on the powder port (non-sterile applications) or by air inflation through the sterile filter (sterile liquid applications). p

21. **Release tri-clamp on powder port.** Begin liquid fill through one of the addition ports to assist in shaft insertion. As bag begins to fill, verify excess film remains behind the bearing port. Pull up additional film if necessary. Once the bag is filled to half working volume with liquid, proceed to the next step for insertion of the drive shaft.

Connect air source to sterile vent filter (Figure 2.22). Begin air inflation through the filter located on the top of the BPC to assist in shaft insertion. As BPC is inflating, ensure it maintains the proper orientation in the support container. It is acceptable to begin filling through one of the addition ports while the BPC is inflating. Proceed to the next step once the BPC panels no longer cling to the impeller tubing in the center of the BPC (filled 1/2 volume with air)—**do not allow the BPC to become tight as it inflates.**





Figure 2.22

Warning: The S.U.M. BPC is not rated as a pressure vessel. The mixer BPC should not be allowed to become tight during inflation. Gas pressure in the BPC should not exceed 0.5 psi (0.03 bar) at any time. Conditions of over pressure may result in BPC damage or personal injury. p

22. Turn off supply of air to the S.U.M. BPC and disconnect air line from filter (if applicable)
23. See Figure 2.23 for a description of the mixing assembly before proceeding to drive shaft insertion.

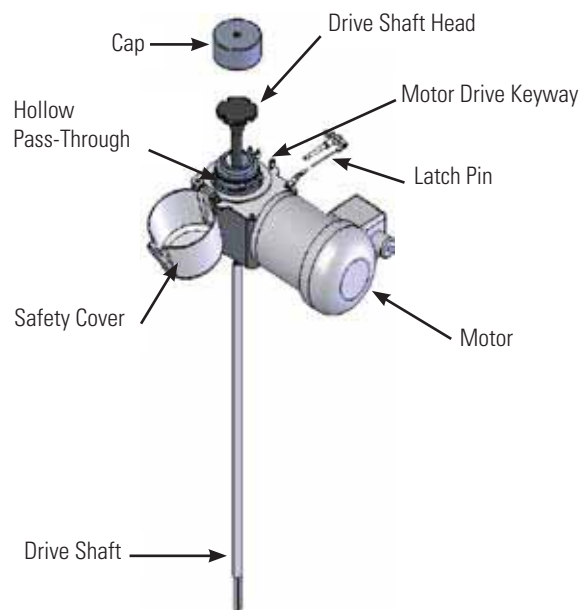


Figure 2.23 Mixing Assembly

NOTE: Care should be taken to keep the drive shaft from impacting the ceiling or ceiling fixtures on removal. Refer to respective data sheets for minimum ceiling height requirements for drive shaft insertion. p

Drive Shaft Insertion

24. Remove the latch pin from the safety cover. Unscrew the threaded cap covering the hollow pass through of the motor (Figure 2.24, 2.25).



Figure 2.24



Figure 2.25

25. Insert drive shaft through hollow pass-through of mixing assembly in the following manner (Figures 2.26, 2.27). **NOTE:** When installing a multi-segment drive shaft, the operator will reverse thread the segments together using the cap latch pin to hold the segment in place while threading.
- Use two hands to load drive shaft through top of mixing assembly; a slight back and forth twisting motion will aid in insertion.
 - When approximately 2" (5.08 cm) of shaft remains, twist slightly to engage impeller.
 - When approximately 1" (2.54 cm) of shaft remains, twist slightly to engage bearing assembly.
 - When approximately 0.25" (0.64 cm) of shaft remains, twist to align motor drive keyway with one of the four outer slots on the drive shaft head.



Figure 2.26



Figure 2.27

26. Directly couple drive shaft to motor drive.
- Place threaded cap on hollow pass-through and hand tighten clockwise.

- Tighten cap by placing spanner wrench on hollow pass-through and tighten cap using supplied torque wrench (Figures 2.28). **NOTE:** The torque wrench is a standard 3/8" square drive, and it is calibrated at the factory at 150 in-lbs.
- Verify wrenches are removed from system and placed in storage holders.
- Close safety access cover and insert latch pin.



Figure 2.28

27. If applicable insert RTD or selected temperature sensor into thermo-well (Figures 2.29, 2.30).
- Place small amount of glycerol (0.5 mL) in well to aid in heat transfer. (Glycerol = Sigma, PN: G6279)
 - Sensor should be inserted until base of probe meets the mouth of the thermo-well.
 - Secure by twisting the luer lock collar (thermo-well will stretch slightly when RTD is seated)



Figure 2.29



Figure 2.30

28. Continue to Section 2.3 for probe preparation and insertion instructions. **Probes should be installed prior to water fill.**

29. At this stage, the remainder of the water can be added to the BPC per formulation instructions. Turn on the motor switch and set the mixer speed with the arrow keys. Verify that the rotation of the drive shaft is counter clockwise when viewed from the top looking down. The S.U.M. is designed to mix in this direction only.

To utilize the S.U.M. hardware for open-top mixing, there are two options. The quickest, most straight forward method is to use the reusable bearing port assembly in the motor block. Alternatively, for the 200, 500, and 1000 L units, the motor sleeve can be changed out to accommodate open-top mixing. See section 2.7 for detailed instructions.

For open-top mixing applications, the S.U.M. setup includes the modified hardware, a single-use impeller sleeve and single-use tank liner with drain line.

Open-Top Mixing Setup

1. Remove liner from protective polybags.
2. Load BPC liner into the S.U.M. hardware by placing the liner inside the outer support container and guiding the drain line through the lower access port and into the bottom slot.
3. Expand the opening of the liner to stretch over the outer rim of the hardware and drape it over the sides.
4. Use the four bottom cut-outs located at the base of the support container as a reference to align positioning tabs on S.U.M. BPC (Figure 2.31). **NOTE:** For the 2000 L and Docking S.U.M. units, hatches are provided in the tanks to facilitate attachment of the positioning tabs to the retention pins.



Figure 2.31

5. Attach platform stretch hooks to each of the four bottom tabs on the BPC (Figure 2.32), or on the corresponding pins on the 2000 L S.U.M. or Docking Station tanks (Figure 2.33).



Figure 2.32



Figure 2.33

6. Once the bag is fully seated, check that the drain line remains fully extended through the bottom port before proceeding to the next step. To keep the drain line from contacting the floor, the line can be guided through one of the bars located on the base of the outer support container.
7. Attach the impeller sleeve directly to the reusable bearing port via the quick connect attachment on the plastic sheath. An audible click will confirm that the attachment is made. (Figure 2.34). **NOTE:** For the 2000 L unit, make the tri-clamp connection (without a gasket) using a plastic clamp.



Figure 2.34

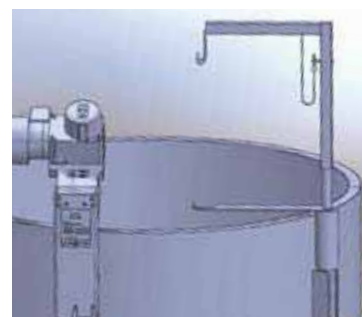


Figure 2.35

8. Insert the drive shaft into the motor as instructed in the previous section.

Powder Addition with the Thermo Scientific HyClone Powdertainer II

The Single-Use Mixer can be equipped with a Powdertainer bag support stand for solids addition (see Section 4.3 for ordering information). The following instructions highlight the HyClone Powdertainer BPC in conjunction with the S.U.M. when equipped with the bag support stand and holding arm. Other methods for solids addition can also utilize the powder port. Complete protocols are not included here as individual protocols vary; however, general descriptions of these processes are

included in Section 2.6. **NOTE:** For the 2000 L and Docking S.U.M. units, a powder arm receiving bracket is already part of the tank. Simply place the powder arm assembly over the bracket (Figure 2.35).

1. Check powder port is locked into the support arm before beginning (Figure 2.36).
2. Suspend Powdertainer BPC from support hanger by the handle (Figure 2.37).
3. Remove clamp and protective cap from powder port on S.U.M. BPC (Figure 2.38). Remove tape and cap from Powdertainer BPC opening.
4. Align Powdertainer opening and powder port.
5. Utilize the tri-clamp provided on the powder port to make the connection (Figure 2.39).
6. To initiate solids addition, release the clamp on the bottom of the feed bag (Figure 2.40). Ensure the entire contents of the feed bag are added before detaching the Powdertainer from the S.U.M. BPC. The powder port cover, gasket and clamp can be replaced if no other dry ingredients are to be added or else left open for pipette sampling.



Figure 2.36



Figure 2.37

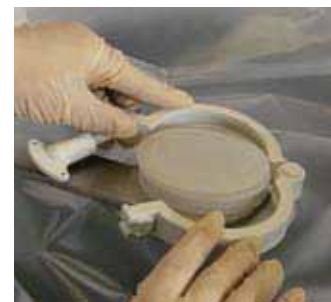


Figure 2.38



Figure 2.39



Figure 2.40

2.4 Probe Assembly

Preparation and Sterilization

1. Select the appropriate probe (see Section 1). Verify the presence of a teflon support ring and o-ring on the probe and visually inspect them for damage.
2. Perform any required probe maintenance and calibrate the pH probe (see Probe Calibration at the end of this section).
3. Place a small amount (0.5-1 mL) of Thermo Scientific HyClone PBS buffer or saline solution onto the threaded end of the probe adaptor.
4. Insert the probe into the probe assembly through the threaded adaptor.
5. Verify the probe tip is not touching ($>1/4''$ [6.35 mm] gap) the membrane of the Kleenpak Connector before threading into probe adaptor.
6. Hand tighten the adaptor and verify the probe tip is not touching the membrane.
7. Place the probe assembly with probe into the autoclave tray for probe kits (Figure 2.41).
8. Autoclave the probe assembly using a validated sterilization cycle (approximately 30 minutes at 122°C). The 30-minute sterilization cycles are generally sufficient. Options of wet or dry cycle parameters can be used. Slow exhaust cycles are preferred as this minimizes stress on the probes during the temperature and pressure changes of autoclaving.
9. When stored properly, the autoclaved probe assemblies can be stored dry for short periods of time (< 24 hr) without loss of sensor longevity, performance or sterility.

NOTE: Before beginning probe insertion, please become familiar with the Kleenpak Connector procedure outlined in Section 2.5. p

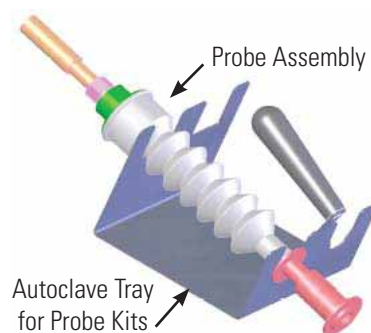


Figure 2.41

Probe Insertion

1. Insert probes into S.U.M. BPC using probe assembly (autoclaved if required).
 - a. Place tubing clamps on all probe ports **prior to attempting to connect probe assemblies** (this will prevent sterility loss in case errors are made during connection of Kleenpak Connectors) (Figure 2.42).



Figure 2.42

- b. Position probe support plate onto outer support container. This holds the probes at a 15 degree incline for best performance (Figure 2.43).



Figure 2.43



Figure 2.44

- c. Connect Kleenpak Connector using protocol outlined by the manufacturer (Section 2.5).
 - d. Ensure all four snaps click on each connector and the base and barrel are fully seated.
 - e. Remove tubing clamp on the individual probe port.
 - f. Insert probe by collapsing bellows toward S.U.M. (Figure 2.44).
 - g. Probe is seated when bellow is fully collapsed. A small amount of fluid may enter the bellow if the probe is loaded after fluid fill.

2. Secure probe by placing connected probe assembly first into probe holder and then locking the holder into the probe support shelf except for probe use with Docking Station tanks. Docking tanks utilize hanging probe holders (clips) rather than holders supported by a shelf.
 - a. Begin by placing the entire collapsed probe assembly in the probe holder starting with the Kleenpak Connector side into the holder side with the short fingers (Figure 2.45 or 2.46).
 - b. If necessary, compress the probe bellows further to allow the probe assembly to be positioned and locked into the other end of the probe holder.
 - c. Allow probe bellows to relax. This secures the probe between the probe holder fingers.
 - d. For shelf use, align probe holder with alignment holes of the probe support shelf (Figure 2.47). For docking tank simply hook the hanging holder into the probe band on the tank (Figure 2.48).
 - e. For shelf use, press the holder downward and into the slots closest to the S.U.M. BPC, then slide the holder backward slightly to lock the probe holder into the probe support shelf.

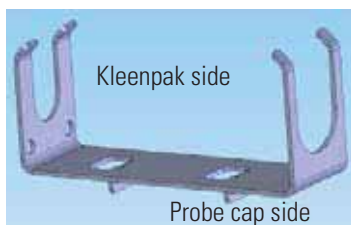


Figure 2.45 Probe holder for use with probe shelf



Figure 2.46 Probe holder for use with probe band



Figure 2.47 Inserting probe holder in shelf slots

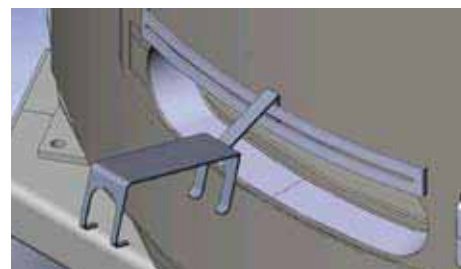


Figure 2.48 Probe holder positioned on probe band

NOTE: Probe ports that are not used prior to fluid fill must remain clamped. Probe ports not used can be accessed later for probe replacement or redundancy purposes if required. p

Probe Calibration

Probe calibration is controller specific. However, for sterile applications, pH probes must be calibrated prior to steam sterilization and the calibration of the probe can be standardized by comparison of an off-line sample once the pH probe is connected to the S.U.M.

2.5 Operating Instructions

Setting Mixing Speeds

1. Once the volume has reached the minimum operating volume of the S.U.M., the mixer control can be turned on via the motor switch.
2. Using the arrow keys, adjust the setpoint speed to the desired level (the red LED display indicates the stirring speed in RPM). Adjust desired mixing rate based on application and liquid volume.
3. Allow speed to stabilize, then make fine adjustments if necessary.
4. Verify the drive shaft rotates counter clockwise.

Recirculation Line Setup

See S.U.M. BPC loading instructions in Section 2.3 for details on setup of the recirculation line.

Mixing Protocols

For generic mixing protocols and procedures, please see Section 2.6.

Fluid Transfer with Quick Connects or Tri-clamp

1. Close clamp on BPC line set.
2. Expose tubing quick connect connection or tri-clamp by tearing perforated seal on protective packaging on the tubing line sets and removing the connector caps (Figure 2.49).
3. Make tubing connection to another line set equipped with size compatible quick connects or tri-clamp (Figure 2.50).
4. Release tubing clamp on BPC line set to permit fluid flow.



Figure 2.49



Figure 2.50

Fluid Transfer with Sterile Tubing Welder

1. Close all clamps on line sets to be connected.
2. Use sterile tubing welder to connect addition/drain line to appropriate BPC line set (Figure 2.51).
3. Inspect welds and open flow path by pinching weld locations.
4. Open clamps on line sets to permit fluid flow.



Figure 2.51

Sampling

Samples can be taken from the SmartSite port on the recirculation loop by attaching a luer lock syringe and drawing a sample while the recirculation loop is operating. Samples can also be taken on those BPCs equipped with a BPC thermo-well/sampling port located in one of the probe ports. Below are instructions for aseptic sampling via the SmartSite port.

Sampling with Recirculation Loop and BPC Sample Port

Using standard luer lock on 60 mL syringe or sterile manifold:

1. Remove dust cover from SmartSite. (Figure 2.52)
2. Clean SmartSite with sanitary wipe.
3. Connect sanitary luer lock type syringe. (Figure 2.53)



Figure 2.52



Figure 2.53

1. Apply small amount of vacuum pressure by pulling out syringe plunger slightly and pull a sample (approximately 30-60 mL).
2. Remove syringe (this will be a purge sample).
3. Clean SmartSite with sanitary wipe.
4. Connect sanitary luer lock type syringe.
5. Apply small amount of vacuum pressure by use of syringe and pull desired sample volume (approximately 10-20 mL).
6. Remove syringe (this will be a representative sample).
7. Clean SmartSite with sanitary wipe and replace dust cap.

Sampling without Recirculation Loop

When the recirculation loop is not being utilized, a line set can be used for sampling. To use a line set for sampling, push the line set down to liquid level and use a pump to draw off liquid into a secondary container. A sample could also be pulled via the drain line in the same manner.

Draining when using the recirculation loop

For applications utilizing the recirculation loop, the line for draining is located on the addition line “Y”. Open the clamp on the 12” [30.5 cm] section of tubing on the recirculation loop “Y” and connect to the intended transfer line. Utilize the peristaltic pump already installed on the recirculation line to transfer the contents of the S.U.M.

Draining without use of the recirculation loop

Draining instructions when not utilizing the recirculation loop:

1. Connect bottom drain tubing set to intended transfer line (for sterile applications this must be done aseptically).
2. Open clamp positioned at the bottom drain port.
3. Begin drain by use of peristaltic pump.
4. When approximately 3–5 liters remain in the BPC, lift the BPC at the top hanging tabs.
5. Hold bottom drain line near floor while lifting top of BPC to facilitate the drain of the final liter of liquid.

S.U.M. Shutdown

1. Once run is complete, verify motor agitation is off and turn off the power to the outer support container by switching off the main power disconnect.
2. If the S.U.M. hardware has come in contact with caustic materials during the course of a run, rinse affected areas with a light water rinse, followed by normal routine cleaning (see below - Preparation for Next Run).
3. Loose items such as the drive shaft, tools and RTD probe should be returned to their storage locations to prevent accidental damage.

For Docking Station Units:

1. Remove drive shaft and bearing port.
2. Release the grapple connection by pushing the handle forward.
3. Release the locking casters.
4. Pull Docking Station away from tank.

Preparation for Next Run

Between runs, the S.U.M. hardware (outer support container, drive shaft and mixer drive, etc.) can be wiped down with sanitary wipes. The outer support container steel surfaces can also be cleaned with stainless steel cleaner. Store drive shaft in storage holder located near the handle of the outer support container. The S.U.M. hardware system is constructed in accordance with IP-54 ratings and can be cleaned to the extent of standard laboratory cleaning procedures. Care should be taken to ensure electrical connections have been disconnected and electrical enclosures are closed tightly. It is also recommended that excess water is not introduced under the control panel. A wipe down with normal disinfectant solutions is sufficient, but without using excessive amounts of liquid. The unit must be allowed to fully dry prior to being brought back into operation.

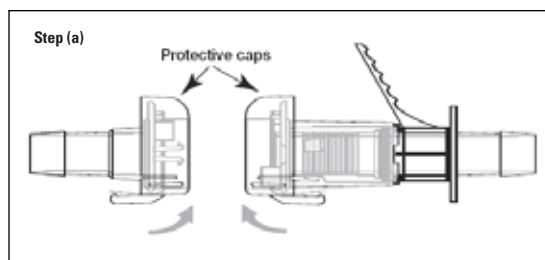
Disposal

Once the S.U.M. is drained, the drive shaft can be removed and stored by reversing steps used during assembly. Please exercise caution when removing the drive shaft from the S.U.M. under low clearance situations. Avoid impacting the drive shaft on the ceiling or ceiling fixtures. See Section 3 for ceiling height recommendations for each volume. The S.U.M. BPC can then be removed from the outer support container. All product contact materials related to the S.U.M. can be disposed of in a waste container or incinerator. If the reusable bearing port has been used for open-top mixing, store it for future use.

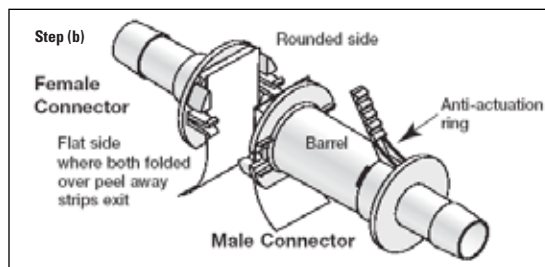
2.6 Pall Kleenpak Connector Instructions

Pall Kleenpak Connector

- a. Lift and pull tab of protective caps to remove caps from connectors.

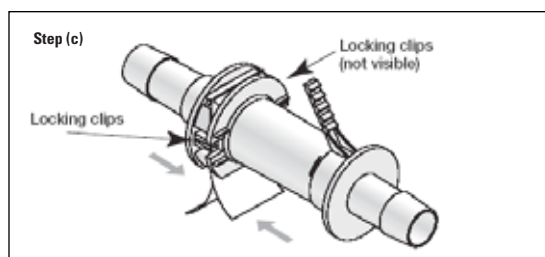


- b. Hold the barrel of the larger (male) connector above the base. Align the smaller (female) connector with the larger (male) connector so both folded white peel away strips are facing the same direction as they exit out the flat sides of the connectors.

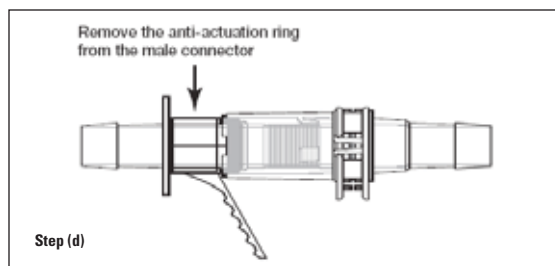


NOTE: Rounded sides must be in alignment and the white peel away strip must remain folded. If the connectors are not aligned properly, the connection cannot be made. The peel away strips must remain folded.

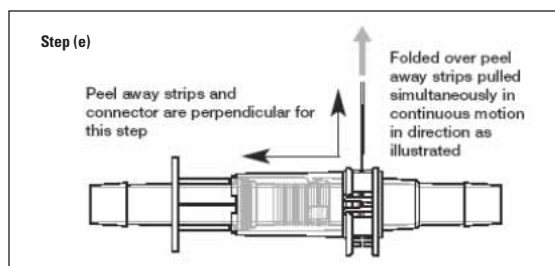
- c. Once aligned correctly, press the two connectors together firmly until both sets of locking clips snap together tightly.



- d. While holding the Kleenpak Connector securely in hand, pull the anti-actuation ring outward.

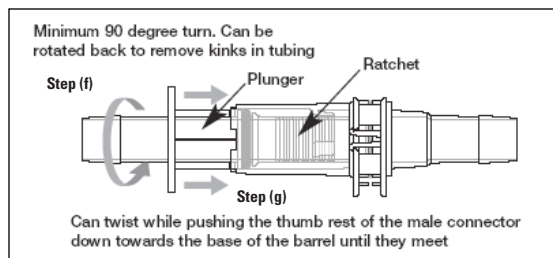


- e. With one hand, hold the barrel of the male connector. Using the other hand, grasp both white peel away strips as close as possible to the flat side of connector to ensure a good grip and pull them out simultaneously in a smooth continuous motion. Ensure the connector is perpendicular to the peel away strips shown in illustration for Step (e). The perpendicular orientation must be maintained while the two strips are pulled simultaneously. Do not use if only one white peel away strip is removed accidentally instead of two; this will affect the sterility of the pathway.

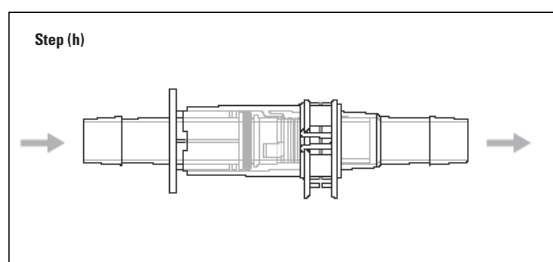


NOTE: Do not impart radial force on the connector. A radial force can cause the connector to break. If a radial force is present due to items attached to the connector, then the connector must be properly supported. p

- f. Rotate the thumb rest on the male connector one full turn at least 90 degrees in the clockwise direction. The rotation serves to bend the anti-actuation tabs which prevent inadvertent engagement. If required, the thumb rest can be turned counterclockwise to remove kinks in the tubing.



- g. Push the thumb rest of the male connector down towards the base of the barrel until they meet. If the thumb rest has not already been turned counterclockwise to remove tubing kinks, the thumb rest can be turned counterclockwise while it is being pushed towards the base of the barrel. Note that in order to establish a proper connection the plunger inside the male connector must be fully inserted into the female connector. As a verification, this normally occurs when the last or second to last ring on the plunger locks into the ratchet. Minimally, the second to last ring must be locked into the ratchet to ensure a proper connection. The thumb rest can be turned one full turn back to re-align tubing, as required, if the second-to-last ring is locked into ratchet. If the plunger has been pushed further than the second-to-last ring, then it may not be possible to turn the thumb rest.



- h. Start the fluid transfer.

2.7 General Mixing Protocols

The following are general examples of mixing protocols that can be utilized with the S.U.M. The protocols are designated as non-sterile and sterile applications. These instructions represent generic operating procedures; individual processes vary from application to application. Consult internal formulation protocols for proper procedures.

pH Probe Calibration

In general, the pH probe calibration (post-autoclave if applicable) can be verified by pulling a sample and analyzing the pH on another calibrated pH meter.

Checkpoints In-Process

Verify the following during mixing:

- „ Mixing speed is at desired setpoint
- „ Cap is tight on drive shaft per specified torque requirements
- „ Casters are locked
- „ Docking Station grapples are locked (if applicable)
- „ Docking Station 3-axis motor positions are locked (if applicable)

Non-Sterile Powder-Liquid or Liquid-Liquid

Water Setup and BPC Preparation

1. Connect the recirculation loop (if desired). Run the drain line through the head of a peristaltic pump and connect drain line to recirculation line. Clamps on line sets should remain closed until the BPC is filled with liquid.
2. Locate the prepared S.U.M. skid on a floor scale and tare the skid on the scale (or use an equivalent volume measurement technique).
3. Connect process water source line to the BPC.
4. Fill the tank with process water to the required volume.
5. Drain the water (either partially or completely) via drain line (supplemental drain if using recirculation loop). If emptying the bag, refill to the level desired (e.g., 90%) before beginning formulation.
6. Once the water level is above the minimum operating volume, the mixer may be turned on.

Addition of Components

Powder-Liquid

1. Suspend the Powdertainer BPC from the hanger with collar support on the S.U.M.
2. Remove clamp, cover and gasket from the powder port on the BPC.
3. Use the holding arm to hold the powder port of the BPC in place as the Powdertainer is positioned.

4. Remove the protective tape and cap from the port on the Powdertainer.
5. Attach the Powdertainer to the powder port on the BPC using the tri-clamp.
6. Verify mixer motor is operating at the desired speed before proceeding.
7. When ready to introduce the powder, open bag clip to release contents of the Powdertainer into the S.U.M. BPC.
8. Continue mixing until all powder is solubilized before proceeding to the next ingredient.
9. Repeat steps 4-8 for all bagged components in the formulation. Additional dry components can be added through the powder port; liquid components can be introduced through the addition lines.
10. Replace cover and clamp on BPC powder port once all ingredients have been added.

Liquid-Liquid

1. Verify mixer motor is operating at the desired speed before proceeding.
2. Ensure clamp on the BPC addition line to be used is closed.
3. If using a pump to deliver the source liquid, load the tubing through the head of the peristaltic pump. Set pump speed and verify fluid flow path.
4. Connect liquid source line to an addition line set on the top of the BPC via the quick connect or tri-clamp fittings.
5. To introduce the liquid, open the flow path by releasing any clamps on the line set and turn on the pump.
6. Continue mixing until all liquid has been introduced before proceeding to the next ingredient.
7. Repeat this process for all liquid components in the formulation.

Sampling

1. Samples can be drawn at any time during the process to verify solubilization, pH, etc. by utilizing the SmartSite port on the recirculation loop (if utilized) or sampling port. Refer to “recirculation/sampling loop operation” section for details.
2. Check the initial pH; adjust pH if necessary using acid or base solutions per formulation procedures.

Quantity Sufficient (Q.S.) Procedures

1. Bring up total volume (if necessary) with additional process water. Carefully monitor the water addition at this stage to ensure proper formulation.
2. Continue mixing per formulation requirements.
3. Check pH and make adjustments if necessary.

Draining

1. Connect supplemental drain line on recirculation loop to collection line using the quick connect. (If not using the recirculation loop for draining, feed the main drain line through the head of the peristaltic pump first).
2. Open clamp on the drain line and turn on pump to remove liquid from the BPC. For sterile applications, filter contents through an inline sterile filter.
3. Agitation must be stopped when volume falls below minimum volume.

Sterile Applications Liquid-Liquid

Water Setup and BPC Preparation

1. Aseptically create the recirculation loop (addition line to drain line) on S.U.M. BPC (if desired).
2. Locate the prepared S.U.M. skid on a floor scale and tare the skid (or use an equivalent volume measurement technique).
3. Aseptically connect sterile water source line to the BPC (sterile tubing welder; quick connects/tri-clamp under laminar flow hood).
4. Fill the tank with process water to the required volume.
5. Drain the water down to desired level (percentage of final volume) (supplemental drain if using recirculation loop). If emptying the bag completely, refill to the level desired before beginning formulation.
6. Once the water level is above the minimum operating volume, the mixer may be turned on.

Addition of Components

1. Verify mixer motor is operating at the desired speed before proceeding.
2. Ensure clamp on the BPC addition line to be used is closed.
3. If using a pump to deliver the source liquid, load the tubing through the head of the peristaltic pump. Set pump speed and verify fluid flow path.
4. Aseptically connect liquid source line to an additional line set on the top of the BPC. If using a sterile tubing welder, open the fluid flow path by pinching the weld points.
5. To introduce the liquid, release any clamps on the line set(s) and turn on the pump.
6. Continue mixing until all liquid has been introduced before proceeding to the next ingredient.
7. Repeat this process for all liquid components in the formulation.

Sampling

1. Samples can be drawn at any time during the process to verify solubilization, pH, etc. by utilizing the SmartSite port on the recirculation loop or sampling port (if utilized). Refer to the recirculation or sampling loop setup instructions in Section 2.3 for details.
2. Check the initial pH; adjust pH if necessary using acid or base solutions per formulation procedures.

Quantity Sufficient (Q.S.) Procedures

1. Bring up total volume (if necessary) with additional process water. Carefully monitor the water addition at this stage to ensure proper formulation.
2. Continue mixing per formulation requirements.
3. Check pH and make adjustments if necessary.

Solution Collection

1. Aseptically connect supplemental drain line on recirculation loop to collection line using the quick connect or sterile tubing welder. (If not using the recirculation loop for draining, feed the drain line through the head of the peristaltic pump first).
2. Open clamp on the drain line and turn on pump to remove liquid from the BPC.
3. Agitation must be stopped when volume falls below minimum volume.

2.8 Open-Top Mixing Hardware Installation

Initial Setup

Always disconnect the S.U.M. from power before starting any mechanical or electrical work.

To accomplish open top mixing in all S.U.M. tanks, simply insert the appropriate reusable bearing port into the bear port receiver of the motor. The 2000 L S.U.M. utilizes the tri-clamp version of the reusable bearing port while all other sizes use the quick connect version (Figure 2.54). Similarly, there are two matching impeller and sleeve combinations, one with the tri-clamp fitting and one with the quick connect fitting (Figure 2.55).



Figure 2.54



Figure 2.55

Figure 2.56 depicts inserting the reusable bearing port into the bearing port receiver. Figure 2.57 demonstrates snapping the quick connect version of the impeller sleeve onto the mating reusable bearing port.



Figure 2.56



Figure 2.57

Section 3 Specifications and Troubleshooting

This section covers the following:

- 3.1 50 L S.U.M. Data Sheet and Specifications
- 3.2 200 L S.U.M. Data Sheet and Specifications
- 3.3 500 L S.U.M. Data Sheet and Specifications
- 3.4 1000 L S.U.M. Data Sheet and Specifications
- 3.5 2000 L S.U.M. Data Sheet and Specifications
- 3.6 Docking S.U.M. Data Sheet and Specifications
- 3.7 Recalibration of the AC-Tech
Variable Speed Drive (SCF/SCM Models)
- 3.8 Troubleshooting

3.1 50 L Single-Use Mixer

- 3.1.1 50 L S.U.M. Data Sheet
- 3.1.2 50 L S.U.M. Hardware Specifications - Non-Heated
- 3.1.3 50 L S.U.M. Hardware Specifications - Water Jacket
- 3.1.4 50 L Control Panel Layout

Thermo Scientific HyClone Single-Use Mixer (S.U.M.) 50 L

The Thermo Scientific HyClone Single-Use Mixer (S.U.M.) is part of a product family which provides efficient and powerful mixing for a wide range of applications based on a conventional stirred tank design. For use with powder hydration for preparation of critical sterile and non-sterile solutions and suspensions.

The current range includes units with maximum volumes of 50, 200, 500, 1000 and 2000 L.

Overview:

The Single-Use Mixer is based on the same concept as the Thermo Scientific HyClone Single-Use Bioreactor (S.U.B.) with a single-use BioProcess Container (BPC®), an integrated impeller and a reusable hardware system providing support, mobility, mixing motor and control system.

The range of product solutions included in this data sheet expand the functionality offered by the original S.U.M. products described in data sheet 033.

These offerings include:

Stainless Steel Hardware Systems

- With or without heating/cooling jacket
- Cutout sections to facilitate S.U.M. BPC loading and monitoring probe capability
- Location mechanism for S.U.M. BPC

S.U.M. BPC Options

- Open top liner media/buffer preparation
- Closed BPC with powder port for contained media/buffer preparation

- Closed BPC with powder port and monitoring probe capability
- Closed BPC for liquid-liquid mixing of critical sterile solutions such as pooling of fractions or processing intermediate solutions
- Closed BPC for liquid-liquid mixing with monitoring probe capability



50 L S.U.M.

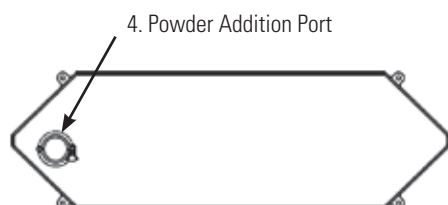
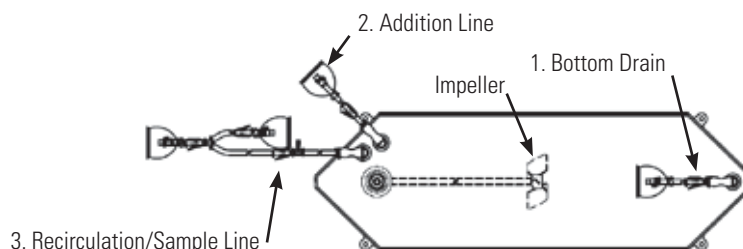
Item	50 L Non-Heated	50 L Water Jacket Heater
Rated Liquid Working Volume	50 L	
Minimum Liquid Working Volume	12 L	
BPC Chamber Diameter	13.75" (34.9 cm)	
BPC Chamber Shoulder Height	33.4" (84.8 cm)	
Liquid Height @ Rated Working Volume	20.5" (52.1 cm)	
Overall Geometry (height/diameter ratio)	1.9:1	
Fluid Geometry @ Working Volume (height/diameter) Ratio	1.5:1	
Impeller (quantity x blade count)	1 x 3	
Impeller Diameter	5.75" (14.6 cm)	
Hold-Up Volume (typical)	<50 mL	
Electrical Power Supply Requirement (voltage, phase, amp)	120 VAC, single, 15 Amp—Non GFCI circuit and 240 VAC, single, 15 Amp—Non GFCI circuit	
Skid Width	26" (66 cm)	
Skid Depth	30" (76.2 cm)	
Skid Height	55.6" (141.2 cm)	
Dry Skid Weight (mass)	340 lbs (154 kg)	365 lbs (165 kg)
Wet Skid Weight—Rated Working Volume (mass)	450 lbs (204 kg)	475 lbs (215 kg)
Minimum Ceiling Height Requirement	8' (244 cm)	
S.U.M. Recommended Operating Parameters		
Temperature	2-40°C	
Motor Speed	0-350 rpm	
Volume Range	20-100% of Nominal	
Maximum Closed Top Mixing Bag Pressure	.2 psig	
Continuous Operating Time	21 days*	

*Mixing time at nominal volume only.

Standard BPC Configurations (CX5-14 Film)

Powder-Liquid Applications—Part number SH30768.01

For use with tubing welder and with CPC® Quick Connects

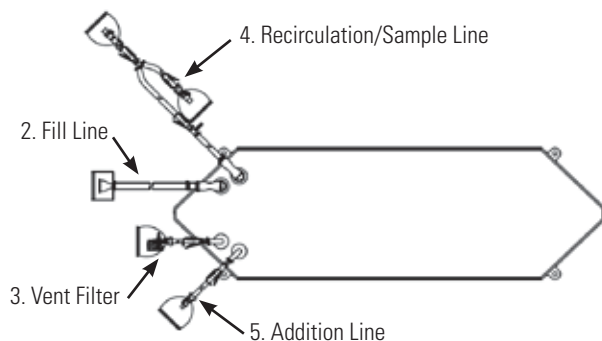
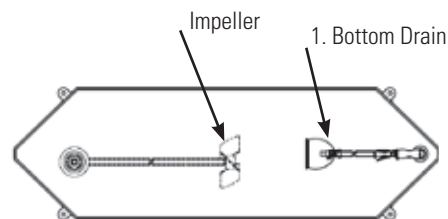
Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex® X 48" (122 cm)	Capped 1/2" (12.7 mm) MPX body
2	Addition Line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Plugged 1/2" (12.7 mm) MPX insert
3	Recirculation/Sample line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 54" (137 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
4	Powder Addition Port	3" (76 mm) Sanitary Fitting, Tri-clamp	Cap with gasket

Standard BPC Configurations (CX5-14 Film)

Liquid-Liquid Applications—Part number SH30767.01

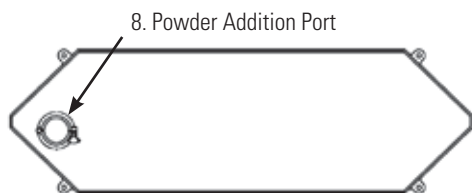
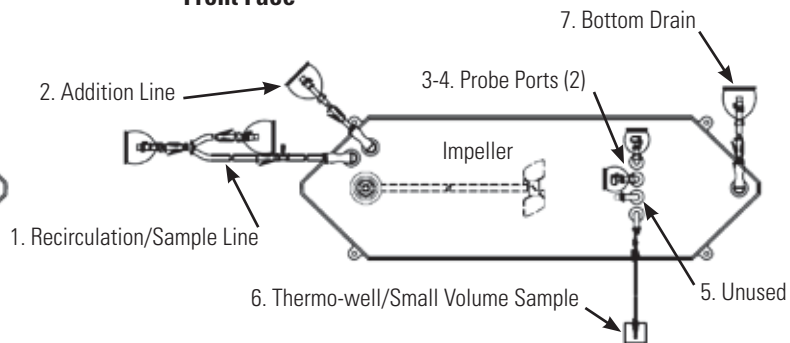
For use with tubing welder and with CPC® Quick Connects

Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Capped 1/2" (12.7 mm) MPX body
2	Fill Line	1/2" (19.1 mm) ID X 3/4" (25.4 mm) OD C-Flex X 48" (122 cm)	1 1/2" (38.1 mm) Tri-clamp SterilEnz™
3	Vent Filter	1/4" (6.4 mm) ID X 1/2" (12.7 mm) OD C-Flex X 4" (10.2 cm)	Sterile Hydrophobic Vent Filter (0.2 micron PVDF - Pall Acro 50)
4	Recirculation/Sample Line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 54" (137 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
5	Addition Line	3/8" (9.5 mm) ID X 5/8" (15.9 mm) OD C-Flex X 24" (61 cm)	Plugged 3/8" (9.5 mm) MPX insert

Standard BPC Configurations (CX5-14 Film)

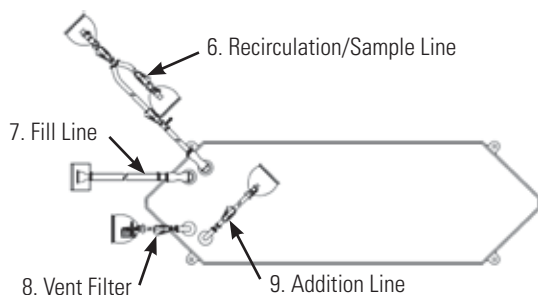
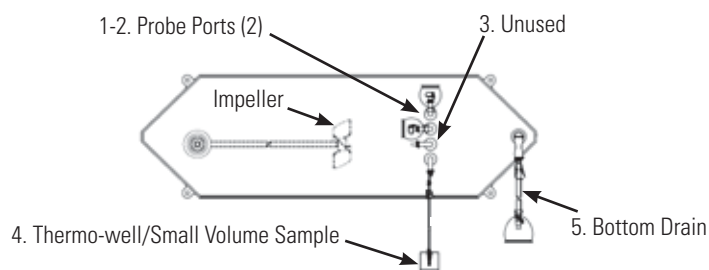
Powder-Liquid Applications with Probe Ports and Thermo-well—Part number SH30768.02
For use with tubing welder and with CPC® Quick Connects

Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Recirculation/Sample line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 54" (137 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
2	Addition Line	1/2" (12.7 mm) ID X 3/4" (15.9 mm) OD C-Flex X 48" (122 cm)	Plugged 1/2" (12.7 mm) MPX insert
3-4	Probe Ports (2)	None	Pall™ Kleenpak™ Aseptic Connector KPCHT Series (Female)
5	Unused	None	Plug
6	Thermo-well/ Small Volume Sample	Thermo-well Adapter for 1/8" (3.2 mm) Diameter 1/8" (3.2 mm) ID X 1/4" (6.4 mm) OD C-Flex X 12" (30 cm)	Luer and SmartSite® Valve Port
7	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Plugged 1/2" (12.7 mm) MPX body
8	Powder Addition Port	3" (76 mm) Sanitary Fitting, Tri-clamp	Cap with gasket

Standard BPC Configurations (CX5-14 Film)

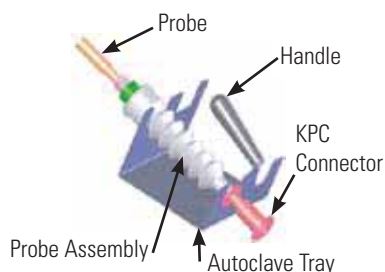
Liquid-Liquid Applications with Probe Ports and Thermo-well—Part number SH30767.02
For use with tubing welder and with CPC® Quick Connects

Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1-2	Probes Ports (2)	None	Pall Kleenpak Aseptic Connector KPCHT Series (Female)
3	Unused	None	Plug
4	Thermo-well/ Small Volume Sample	Thermo-well Adapter for 1/8" (3.2 mm) Diameter 1/8" (3.2 mm) ID X 1/4" (6.4 mm) OD C-Flex X 12" (30 cm)	Luer and SmartSite Valve Port
5	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Capped 1/2" (1.27 cm) MPX body
6	Recirculation/Sample Line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
7	Fill Line	1/2" (19.1 mm) ID X 3/4" (25.4 mm) OD C-Flex X 48" (122 cm)	1 1/2" Tri-clamp SterilEnz
8	Vent Filter	1/4" (6.4 mm) ID X 1/2" (12.7 mm) OD C-Flex X 4" (10.2 cm)	Sterile Hydrophobic Vent Filter (0.2 micron PVDF - Pall Acro 50)
9	Addition Line	3/8" (9.5 mm) ID X 5/8" (15.9 mm) OD C-Flex X 24" (61 cm)	Plugged 3/8" (9.5 mm) MPX insert

Ordering Information for Standard Products

Autoclave Tray and Probe Kits:

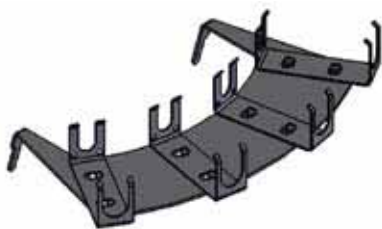


Additional Information on Autoclave Tray:

- Fabricated from stainless steel
- Plastic carry handle for easy transport right out of the autoclave
- Positions probes on 15% incline for greater probe/membrane longevity
- Will restrain probe bellows from collapsing during sterilization
- Probe holder accommodates two probes

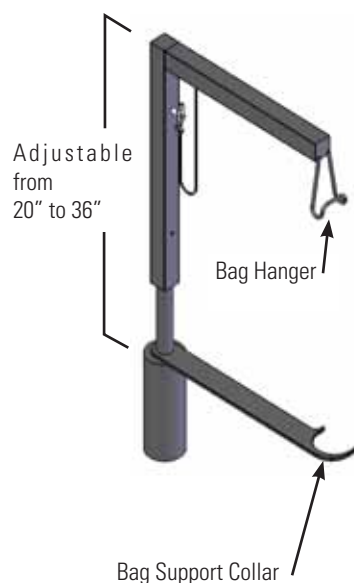
Probe Shelf:

The S.U.M. can be equipped with a probe shelf for probe support and retention.



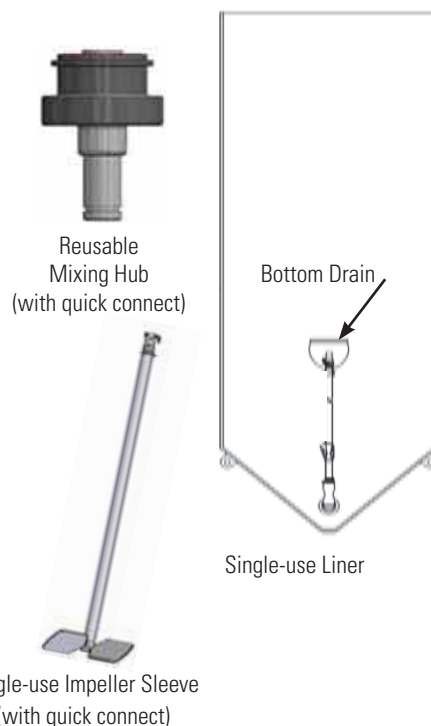
Powdertainer Hanger:

The Single-Use Mixer (S.U.M.) can be equipped with a Thermo Scientific HyClone Powdertainer Hanger if so desired. When adding solids to liquids, this optional feature enables utilization of the Powdertainer powder feed system. The Powdertainer hanger can be used to support full 1, 5 or 25 Kg Powdertainers and positions the 3" sanitary connectors for bag to bag connection and solids transfer.



Open-Top Mixing (OTM) use:

The S.U.M. can be equipped with a reusable mixing hub accessory to enable use of open top liners and single-use impeller sleeves. The OTM option is a non-sterile easy-to-use mixing option. The reusable hub is simply placed into the motor's bearing port receiver and latched into place. The single-use impeller sleeve attaches to the hub's quick connect end. With an open liner in position and a drive shaft inserted the system is ready to use.



Accessories

Part Number	Description	
SH30720.01	Probe Assembly (non-sterile)	Used to package probes (not supplied) for sterilization and to aseptically connect them to the S.U.M. BPC.
SV20664.01	Heavy Duty Tubing Clamp	Reusable tubing clamp used on probe ports when connecting probe assembly.
SV20664.02	Heavy Duty Tubing Clamp (4 pack of SV20664.01)	
SV20664.03	Heavy Duty Tubing Clamp (10 pack of SV20664.01)	
SV20750.01	S.U.M. thermo-well/sample port	Used for RTD calibration/validation.
SV20778.01	RTD	Pt100 Resistance Temperature Detector for use with S.U.M BPC thermo-well/sampling port.
SV50177.01	Autoclave Tray for Probe Kits (stainless steel)	Support tray which allows the probes to be safely autoclaved.
SH30845.01	Sterile Sampling Manifold with luer lock (individual)	Available for aseptic luer connection or welding onto the sample line to take sample sets.
SH30845.02	Sterile Sampling Manifold with luer lock (10 pack)	
SV50194	Load Cells*	Installed by manufacturer or end-user
SV50177.29	Probe Shelf	Support shelf for use with probe assemblies.
SV50187.01	Powdertainer Hanger with Support Collar	To support BPCs during Powdertainer attachment
SV50177.77	Reusable Mixing Hub	Required for use with single-use impeller sleeve
SH30762.04	Single-use Liner	Bottom drain liner with 72" (182.9 cm) of ½" (12.7 mm) C-Flex tubing and an MPX insert connector, CX3-9 Film
SH30749.06	Single-use Impeller Sleeve	For Open-Top Mixing

* For more information on Load Cell options refer to Data Sheet 048.

Hardware Standard Products

Non Heated:

Part Number	Description	
SV50212.01	50 L S.U.M., (120 VAC, Single Phase)	Includes: 304 stainless steel outer support container with swivel caster platform, variable speed agitation controller, motor, drive assembly with shaft and standard tool set.
SV50212.02	50 L S.U.M., (240 VAC, Single Phase)	

Water Jacket:

Part Number	Description	
SV50212.03	50 L S.U.B., (120 VAC, Single Phase)	Includes: 304 stainless steel outer support container with swivel caster platform, variable speed agitation controller, motor, drive assembly with shaft, integrated water jacket and standard tool set.
SV50212.04	50 L S.U.B., (240 VAC, Single Phase)	

Custom BPC Options:

Tubing Type	C-Flex® (clear, white and ADCF), Silicone, PVC, PharMed® or PharmaPure®
Tubing Size	Specific Lengths of 1/8 to 1" (3.18 to 25.4 mm) ID - depending on type of tubing chosen
Connectors	Luer — 1/8 to 1/2" (3.18 to 12.7 mm) ID CPC — 1/4 to 3/4" (6.35 to 19 mm) ID SIP Connector — 1/4 to 3/4" (6.35 to 19 mm) ID Triclamp — 1/8" to 1" (3.18—25.4mm) ID Mini-Triclamp — 1/8 to 1/2" (6.35 to 12.7 mm) ID Aseptic Connection Device — All available sizes of Pall Kleenpak and BioQuate DAC
Others	Needle-free sample port (Smartsite or Clave®) Filter Capsule (Millipore, Pall, Sartorius, Domnick Hunter, Meissner, Other)

Please Note: Not all options are available for all ports. No customization of port type and location, chamber dimensions or mixing assembly is possible. For additional information, please refer to the Selection Guides in the 2008 BPC Catalog.

Presentation (as dry BPC systems):

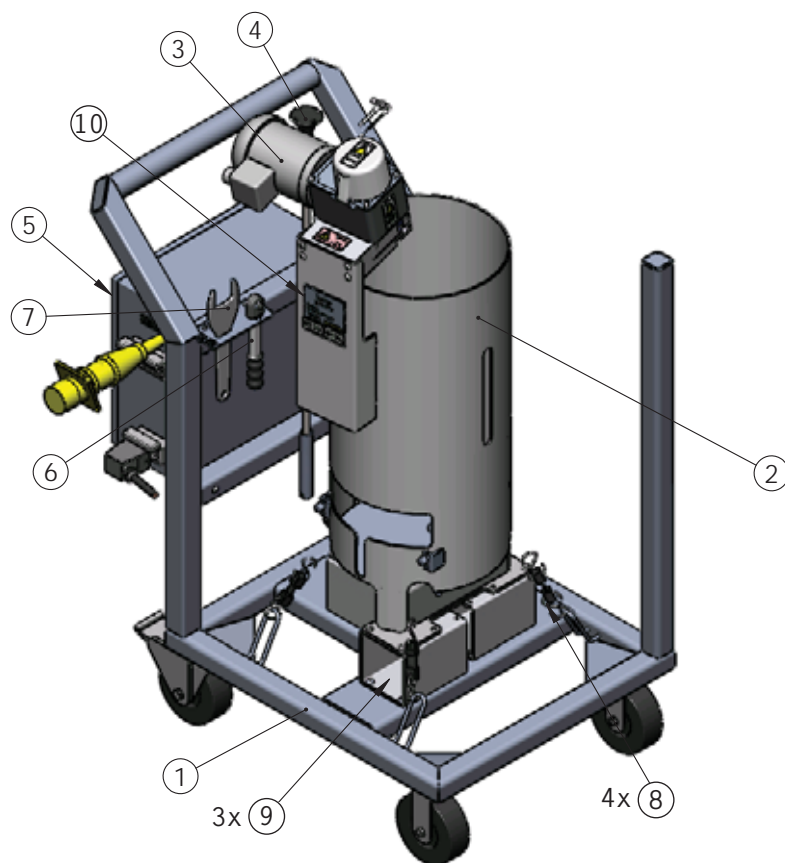
Outer Packaging	Supplied 'flat-packed' Two polyethylene outer layers
Label	Description Product code Lot number Expiry date on outer packaging and shipping container
Sterilization	Irradiation (25 to 38 kGy) inside outer packaging
Shipping Container	Durable cardboard carton
Documentation	Certificate of Analysis provided with each lot for each delivery

Hardware Features

50 L S.U.M.:

The stainless steel outer support container contains the following features:

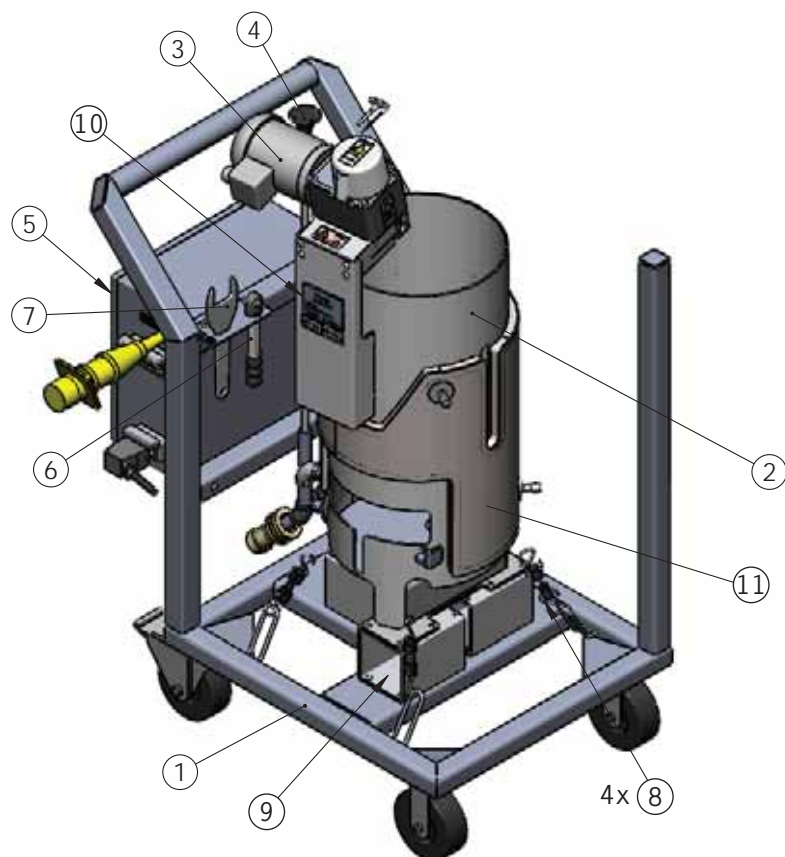
1. Platform with large diameter wheels
2. Stainless steel (304) outer support container
3. Mixer motor
4. Drive shaft
5. Control Panel
6. Pre-set torque wrench
7. Spanner wrench
8. 4 x Stretch Hooks
9. 3 x Spacer blocks - replaceable with load cells
10. ID plate



50 L S.U.M. Jacket:

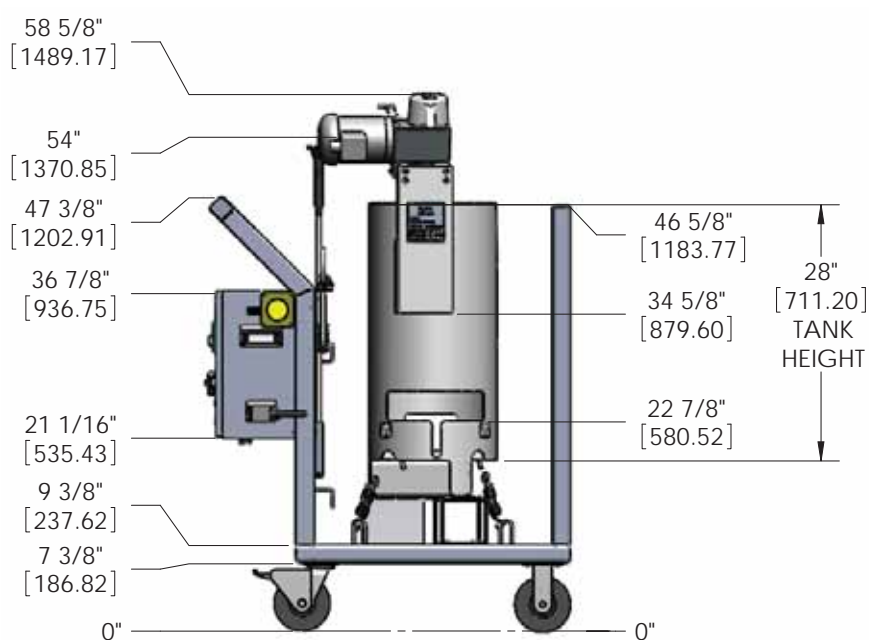
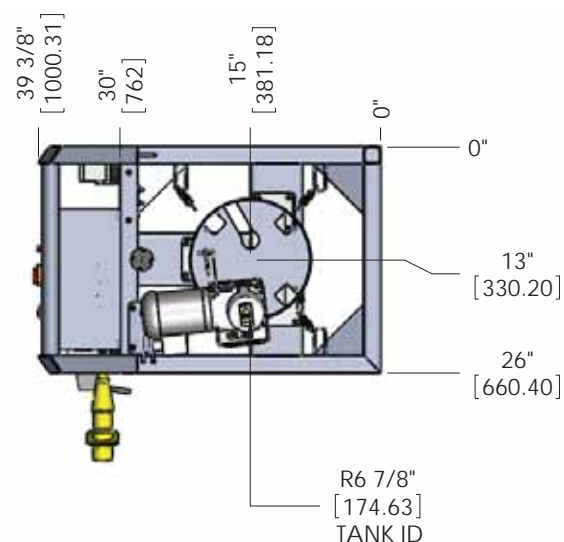
The stainless steel outer support container contains the following features:

1. Platform with large diameter wheels
2. Stainless steel (304) outer support container
3. Mixer motor
4. Drive shaft
5. Control Panel
6. Pre-set torque wrench
7. Spanner wrench
8. 4 x Stretch Hooks
9. 3 x Spacer blocks - replaceable with load cells
10. ID plate
11. Water jacket

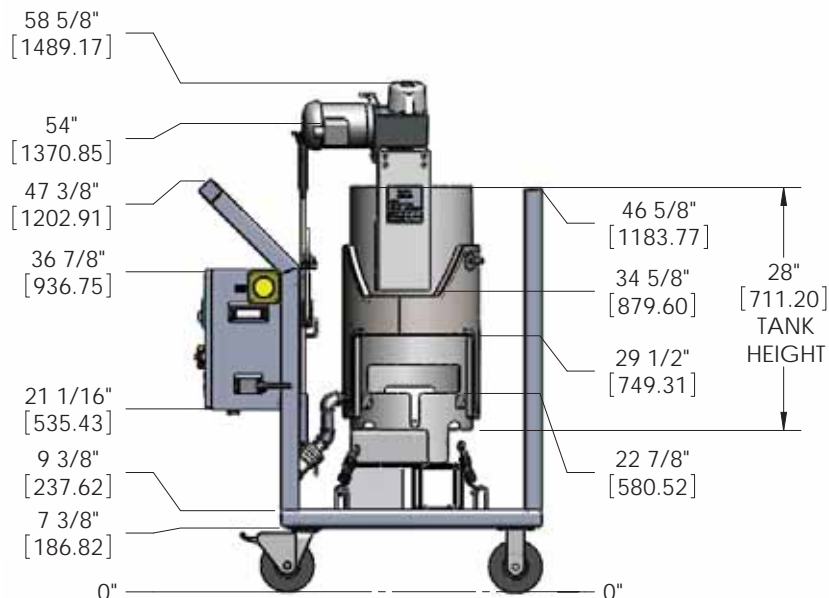
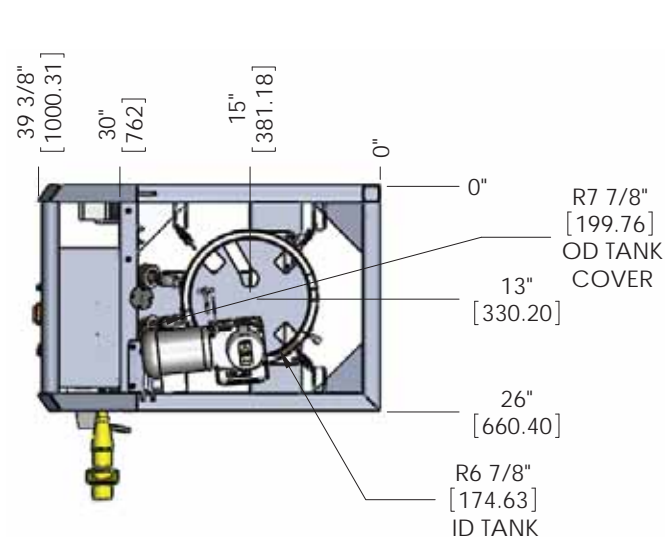


Outer Support Container (units in inches [mm])

50 L S.U.M.:



50 L Jacketed S.U.M.:



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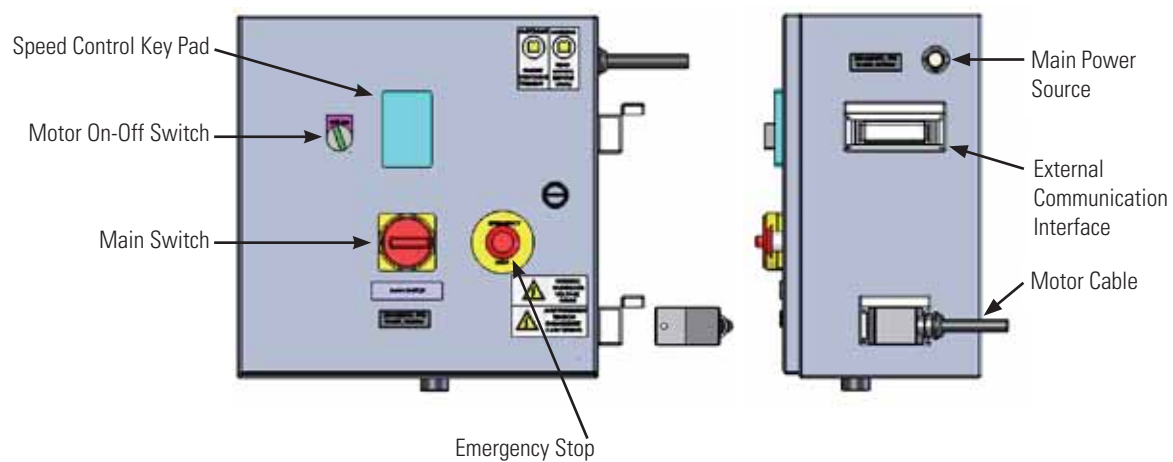
3.1.2 50 L Hardware Specifications Non-Heated

Vessel Geometry	Rated Liquid Working Volume	50 L
	Minimum Liquid Working Volume	12 L
	BPC Chamber Diameter	13.75" (34.9 cm)
	BPC Chamber Shoulder Height	33.4" (84.8 cm)
	Liquid Height @ Rated Working Volume	20.5" (52.1 cm)
	Fluid Geometry @ Working Volume (height/diameter) Ratio	1.5:1
	Overall Geometry (height/diameter) Ratio	1.9:1
	Hold up volume (typical)	<50 mL
Impeller	Impeller (quantity X blade count)	1 x 3
	Impeller Blade Pitch (angle)	45°
	Impeller Diameter	5.75" (14.6 cm)
Mixing	Maximum Mixing Rate (revolutions per minute)	350 RPM
	Overall Drive Shaft Length	36.1" (91.7 cm)
Drive Motor	Programmable VFD, Remote Panel Interface	Standard
	Mixer Motor Drive (voltage, phase, amp)	208 VAC, three, 15 Amp
	Motor Power Rating	0.5 hp (372.8 W)
	Motor Torque Rating	80 in-lbs (9.04 Nm)
	Gear Reduction	5:1
Support Container	Primary Construction Material (Outer Support Container)	304 Stainless Steel
	Primary Construction Material (Inner Support Tank)	304 Stainless Steel
	Skid Width	26" (66 cm)
	Skid Depth	30" (76.2 cm)
	Skid Height	55.6" (141.2 cm)
	Dry Skid Weight (mass)	340 lbs (154 kg)
	Wet Skid Weight - Rated Working Volume (mass)	450 lbs (204 kg)
General	Minimum Ceiling Height Recommendations	8' (244 cm)
	Electrical Power Supply Requirement (voltage, phase, amp)	120 or 240 VAC, single, 15 Amp Non GFCI circuit
	Electrical Class Ratings	ETL, CE, IP-56
	Contact Materials Biocompatibility	USP Class VI
	Validated System Reliability (minimum)	0.9 @ 90%
	Weigh Scale Platform Area (minimum area for caster stands)	21" x 25"

3.1.3 50 L Hardware Specifications Water Jacket

Vessel Geometry	Rated Liquid Working Volume	50 L
	Minimum Liquid Working Volume	12 L
	BPC Chamber Diameter	13.75" (34.9 cm)
	BPC Chamber Shoulder Height	33.4" (84.8 cm)
	Liquid Height @ Rated Working Volume	20.5" (52.1 cm)
	Fluid Geometry @ Working Volume (height/diameter) Ratio	1.5:1
	Overall Geometry (height/diameter) Ratio	1.9:1
	Hold up volume (typical)	<50 mL
Impeller	Impeller (quantity X blade count)	1 x 3
	Impeller Blade Pitch (angle)	45°
	Impeller Diameter	5.75" (14.6 cm)
Mixing	Maximum Mixing Rate (revolutions per minute)	350 RPM
	Overall Drive Shaft Length	36.1" (91.7 cm)
Drive Motor	Programmable VFD, Remote Panel Interface	Standard
	Mixer Motor Drive (voltage, phase, amp)	208 VAC, three, 15 Amp
	Motor Power Rating	0.5 hp (372.8 W)
	Motor Torque Rating	82 in-lbs (9.5 Nm)
	Gear Reduction	5:1
Support Container	Primary Construction Material (Outer Support Container)	304 Stainless Steel
	Primary Construction Material (Inner Support Tank)	304 Stainless Steel
	Skid Width	26" (66 cm)
	Skid Depth	30" (76.2 cm)
	Skid Height	55.6" (141.2 cm)
	Dry Skid Weight (mass)	365 lbs (165 kg)
	Wet Skid Weight - Rated Working Volume (mass)	475 lbs (215 kg)
General	Minimum Ceiling Height Recommendations	8' (244 cm)
	Electrical Power Supply Requirement (voltage, phase, amp)	120 or 240 VAC, single, 15 Amp Non GFCI circuit
	Electrical Class Ratings	ETL, CE, IP-56
	Contact Materials Biocompatibility	USP Class VI
	Validated System Reliability (minimum)	0.9 @ 90%
	Weigh Scale Platform Area (minimum area for caster stands)	21" x 25"

3.1.4 50 L Control Panel Layout



3.2 200 L Single-Use Mixer

3.2.1	200 L S.U.M. Data Sheet
3.2.2	200 L S.U.M. Hardware Specifications - Non-Heated
3.2.3	200 L S.U.M. Hardware Specifications - Water Jacket
3.2.4	200 L Control Panel Layout

Thermo Scientific HyClone Single-Use Mixer (S.U.M.) 200 L

The Thermo Scientific HyClone Single-Use Mixer (S.U.M.) is part of a product family which provides efficient and powerful mixing for a wide range of applications based on a conventional stirred tank design. For use with powder hydration for preparation of critical sterile and non-sterile solutions and suspensions.

The current range includes units with maximum volumes of 50, 200, 500, 1000 and 2000 L.

Overview:

The Single-Use Mixer is based on the same concept as the Thermo Scientific HyClone Single-Use Bioreactor (S.U.B.) with a single-use BioProcess Container (BPC®), an integrated impeller and a reusable hardware system providing support, mobility, mixing motor and control system.

The range of product solutions included in this data sheet expand the functionality offered by the original S.U.M. products described in data sheet 033.

These offerings include:

Stainless Steel Hardware Systems

- With or without heating/cooling jacket
- Cutout sections to facilitate S.U.M. BPC loading and monitoring probe capability
- Location mechanism for S.U.M. BPC

S.U.M. BPC Options

- Open top liner media/buffer preparation
- Closed BPC with powder port for contained media/buffer preparation

- Closed BPC with powder port and monitoring probe capability
- Closed BPC for liquid-liquid mixing of critical sterile solutions such as pooling of fractions or processing intermediate solutions
- Closed BPC for liquid-liquid mixing with monitoring probe capability



200 L S.U.M.

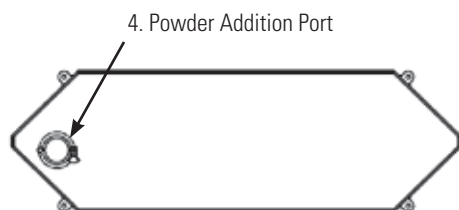
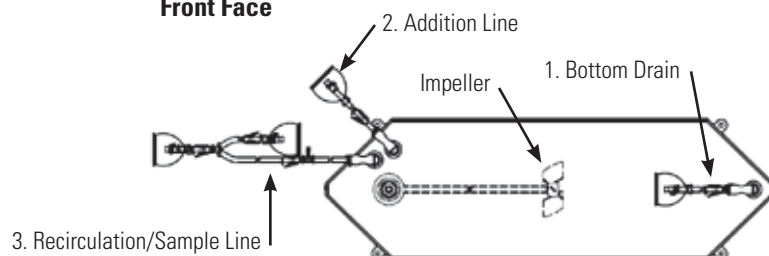
Item	200 L Non-Heated	200 L Water Jacket Heater
Rated Liquid Working Volume	200 L	
Minimum Liquid Working Volume	40 L	
BPC Chamber Diameter	20" (50.8 cm)	
BPC Chamber Shoulder Height	48.6" (123.4 cm)	
Liquid Height @ Rated Working Volume	39" (99 cm)	
Overall Geometry (height/diameter ratio)	1.95:1	
Fluid Geometry @ Working Volume (height/diameter) Ratio	2.2:1	
Impeller (quantity x blade count)	1 x 3	
Impeller Diameter	7.875" (20 cm)	
Hold-Up Volume (typical)	<50 mL	
Electrical Power Supply Requirement (voltage, phase, amp)	120 VAC, single, 15 Amp—Non GFCI circuit and 240 VAC, single, 15 Amp—Non GFCI circuit	
Skid Width	32.5" (82.6 cm)	
Skid Depth	47" (119.4 cm)	
Skid Height	71" (157.5 cm)	
Dry Skid Weight (mass)	504 lbs (229 kg)	527 lbs (239 kg)
Wet Skid Weight—Rated Working Volume (mass)	946 lbs (429 kg)	969 lbs (439 kg)
Minimum Ceiling Height Requirement	10' (305 cm)	
S.U.M. Recommended Operating Parameters		
Temperature	2-40°C	
Motor Speed	0-350 rpm	
Volume Range	20-100% of Nominal	
Maximum Closed Top Mixing Bag Pressure	.2 psig	
Continuous Operating Time	21 days*	

*Mixing time at nominal volume only.

Standard BPC Configurations (CX5-14 Film)

Powder-Liquid Applications—Part number SH30750.01

For use with tubing welder and with CPC® Quick Connects

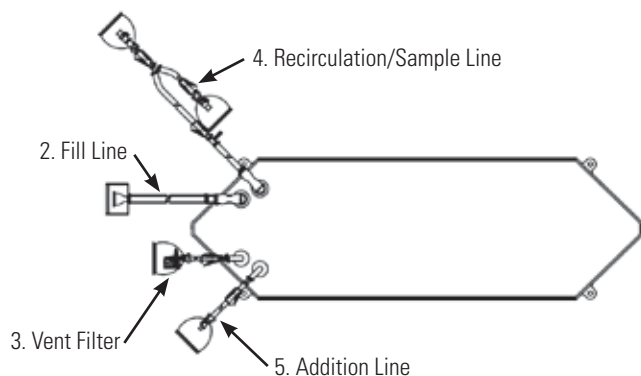
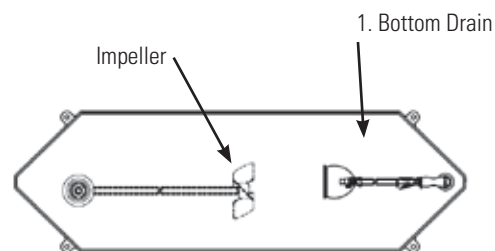
Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex® X 48" (122 cm)	Capped 1/2" (12.7 mm) MPX insert
2	Addition Line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Plugged 1/2" (12.7 mm) MPX body
3	Recirculation/Sample line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 54" (137 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
4	Powder Addition Port	3" (76 mm) Sanitary Fitting, Tri-clamp	Cap with gasket

Standard BPC Configurations (CX5-14 Film)

Liquid-Liquid Applications—Part number SH30753.01

For use with tubing welder and with CPC® Quick Connects

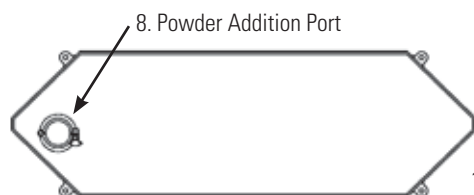
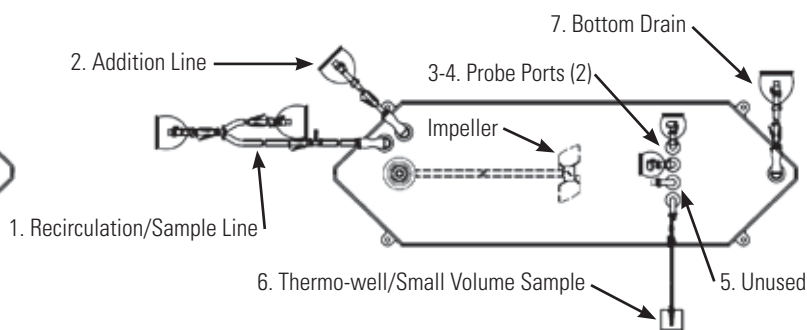
Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Capped 1/2" (12.7 mm) MPX insert
2	Fill Line	3/4" (19.1 mm) ID X 1" (25.4 mm) OD C-Flex X 48" (122 cm)	1 1/2" (38.1 mm) Tri-clamp SterilEnz™
3	Vent Filter	1/4" (6.4 mm) ID X 1/2" (12.7 mm) OD C-Flex X 4" (10.2 cm)	Sterile Hydrophobic Vent Filter (0.2 micron PVDF - Pall Acro 50)
4	Recirculation/Sample Line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 54" (137 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
5	Addition Line	3/8" (9.5 mm) ID X 5/8" (15.9 mm) OD C-Flex X 24" (61 cm)	Plugged 3/8" (9.5 mm) MPX body

Standard BPC Configurations (CX5-14 Film)

Powder-Liquid Applications with Probe Ports and Thermo-well—Part number SH30750.02

For use with tubing welder and with CPC® Quick Connects

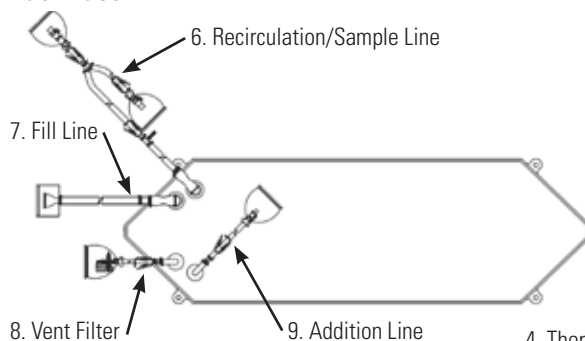
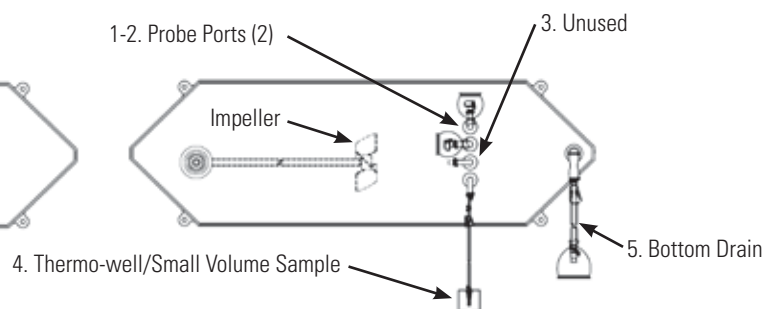
Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Recirculation/Sample line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 54" (137 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
2	Addition Line	1/2" (12.7 mm) ID X 5/8" (15.9 mm) OD C-Flex X 48" (122 cm)	Plugged 1/2" (12.7 mm) MPX body
3-4	Probe Ports (2)	None	Pall™ Kleenpak™ Aseptic Connector KPCHT Series (Female)
5	Unused	None	Plug
6	Thermo-well/ Small Volume Sample	Thermo-well Adapter for 1/8" (3.2 mm) Diameter 1/8" (3.2 mm) ID X 1/4" (6.4 mm) OD C-Flex X 12" (30 cm)	Luer and SmartSite® Valve Port
7	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Plugged 1/2" (12.7 mm) MPX body
8	Powder Addition Port	3" (76 mm) Sanitary Fitting, Tri-clamp	Cap with gasket

Standard BPC Configurations (CX5-14 Film)

Liquid-Liquid Applications with Probe Ports and Thermo-well—Part number SH30753.02

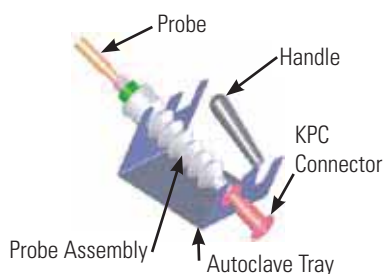
For use with tubing welder and with CPC® Quick Connects

Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1-2	Probes Ports (2)	None	Pall Kleenpak Aseptic Connector KPCHT Series (Female)
3	Unused	None	Plug
4	Thermo-well/ Small Volume Sample	Thermo-well Adapter for 1/8" (3.2 mm) Diameter 1/8" (3.2 mm) ID X 1/4" (6.4 mm) OD C-Flex X 12" (30 cm)	Luer and SmartSite Valve Port
5	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Capped 1/2" (1.27 cm) MPX insert
6	Recirculation/Sample Line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
7	Fill Line	3/4" (19.1 mm) ID X 1" (25.4 mm) OD C-Flex X 48" (122 cm)	1 1/2" Tri-clamp SterilEnz
8	Vent Filter	1/4" (6.4 mm) ID X 1/2" (12.7 mm) OD C-Flex X 4" (10.2 cm)	Sterile Hydrophobic Vent Filter (0.2 micron PVDF - Pall Acro 50)
9	Addition Line	3/8" (9.5 mm) ID X 5/8" (15.9 mm) OD C-Flex X 24" (61 cm)	Plugged 3/8" (9.5 mm) MPX body

Ordering Information for Standard Products

Autoclave Tray and Probe Kits:

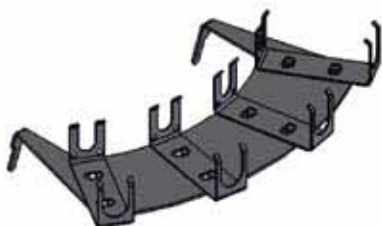


Additional Information on Autoclave Tray:

- Fabricated from stainless steel
- Plastic carry handle for easy transport right out of the autoclave
- Positions probes on 15% incline for greater probe/membrane longevity
- Will restrain probe bellows from collapsing during sterilization
- Probe holder accommodates two probes

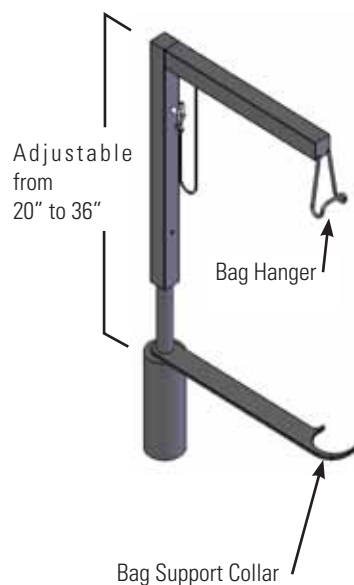
Probe Shelf:

The S.U.M. can be equipped with a probe shelf for probe support and retention.



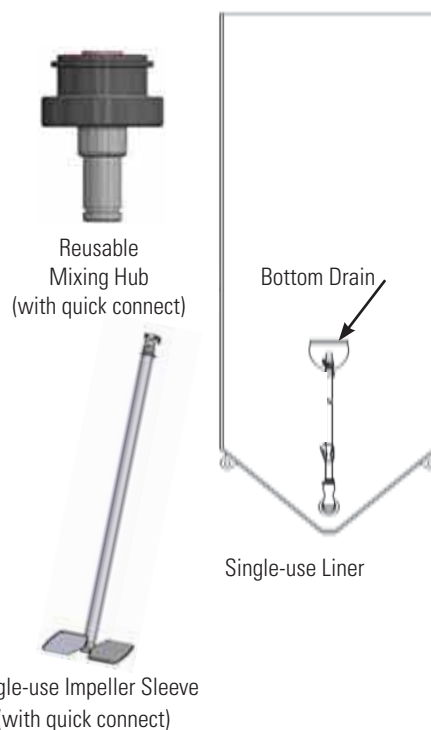
Powdertainer Hanger:

The Single-Use Mixer (S.U.M.) can be equipped with a Thermo Scientific HyClone Powdertainer Hanger if so desired. When adding solids to liquids, this optional feature enables utilization of the Powdertainer powder feed system. The Powdertainer hanger can be used to support full 1, 5 or 25 Kg Powdertainers and positions the 3" sanitary connectors for bag to bag connection and solids transfer.



Open-Top Mixing (OTM) use:

The S.U.M. can be equipped with a reusable mixing hub accessory to enable use of open top liners and single-use impeller sleeves. The OTM option is a non-sterile easy-to-use mixing option. The reusable hub is simply placed into the motor's bearing port receiver and latched into place. The single-use impeller sleeve attaches to the hub's quick connect end. With an open liner in position and a drive shaft inserted the system is ready to use.



Accessories

Part Number	Description	
SH30720.01	Probe Assembly (non-sterile)	Used to package probes (not supplied) for sterilization and to aseptically connect them to the S.U.M. BPC.
SV20664.01	Heavy Duty Tubing Clamp	Reusable tubing clamp used on probe ports when connecting probe assembly.
SV20664.02	Heavy Duty Tubing Clamp (4 pack of SV20664.01)	
SV20664.03	Heavy Duty Tubing Clamp (10 pack of SV20664.01)	
SV20750.01	S.U.M. thermo-well/sample port	Used for RTD calibration/validation.
SV20778.01	RTD	Pt100 Resistance Temperature Detector for use with S.U.M BPC thermo-well/sampling port.
SV50177.01	Autoclave Tray for Probe Kits (stainless steel)	Support tray which allows the probes to be safely autoclaved.
SH30845.01	Sterile Sampling Manifold with luer lock (individual)	Available for aseptic luer connection or welding onto the sample line to take sample sets.
SH30845.02	Sterile Sampling Manifold with luer lock (10 pack)	
SV50193	Load Cells*	Installed by manufacturer or end-user
SV50177.93	Probe Shelf	Support shelf for use with probe assemblies.
SV50187.01	Powdertainer Hanger with Support Collar	To support BPCs during Powdertainer attachment
SV50177.77	Reusable Mixing Hub	Required for use with single-use impeller sleeve
SH30762.01	Single-use Liner	Bottom drain liner with 72" (182.9 cm) of ½" (12.7 mm) C-Flex tubing and an MPX insert connector, CX3-9 Film
SH30749.08	Single-use Impeller Sleeve	For Open-Top Mixing

* For more information on Load Cell options refer to Data Sheet 048.

Hardware Standard Products

Non-Heated:

Part Number	Description	
SV50213.01	200 L S.U.M., (120 VAC, Single Phase)	Includes: 304 stainless steel outer support container with swivel caster platform, variable speed agitation controller, motor, drive assembly with shaft and standard tool set.
SV50213.02	200 L S.U.M., (240 VAC, Single Phase)	

Water Jacket:

Part Number	Description	
SV50213.03	200 L S.U.B., (120 VAC, Single Phase)	Includes: 304 stainless steel outer support container with swivel caster platform, variable speed agitation controller, motor, drive assembly with shaft, integrated water jacket and standard tool set.
SV50213.04	200 L S.U.B., (240 VAC, Single Phase)	

Custom BPC Options:

Tubing Type	C-Flex (clear, white, and ADCF), Silicone, PVC, PharMed® or PharmaPure®
Tubing Size	Specific Lengths of 1/8 to 1" (3.18 to 25.4 mm) ID — depending on type of tubing chosen
Connectors	Luer — 1/8 to 1/2" (3.18 to 12.7 mm) ID CPC — 1/4 to 3/4" (6.35 to 19 mm) ID SIP Connector — 1/4 to 3/4" (6.35 to 19 mm) ID Tri-clamp — 1/8" to 1" (3.18 to 25.4mm) ID Mini-Tri-clamp — 1/8 to 1/2" (6.35 to 12.7 mm) ID Aseptic Connection Device — All available sizes of Pall Kleenpak and BioQuate™ DAC
Others	Needle-free sample port (SmartSite or Clave®) Filter Capsule (Millipore®, Pall, Sartorius™, Domnick Hunter®, Meissner®, Other)

Please Note: Not all options are available for all ports. Customization of port type and location, chamber dimensions or mixing assembly is not available. For additional information, please refer to the Selection Guides in the 2008 BPC Catalog.

Presentation (as dry BPC systems):

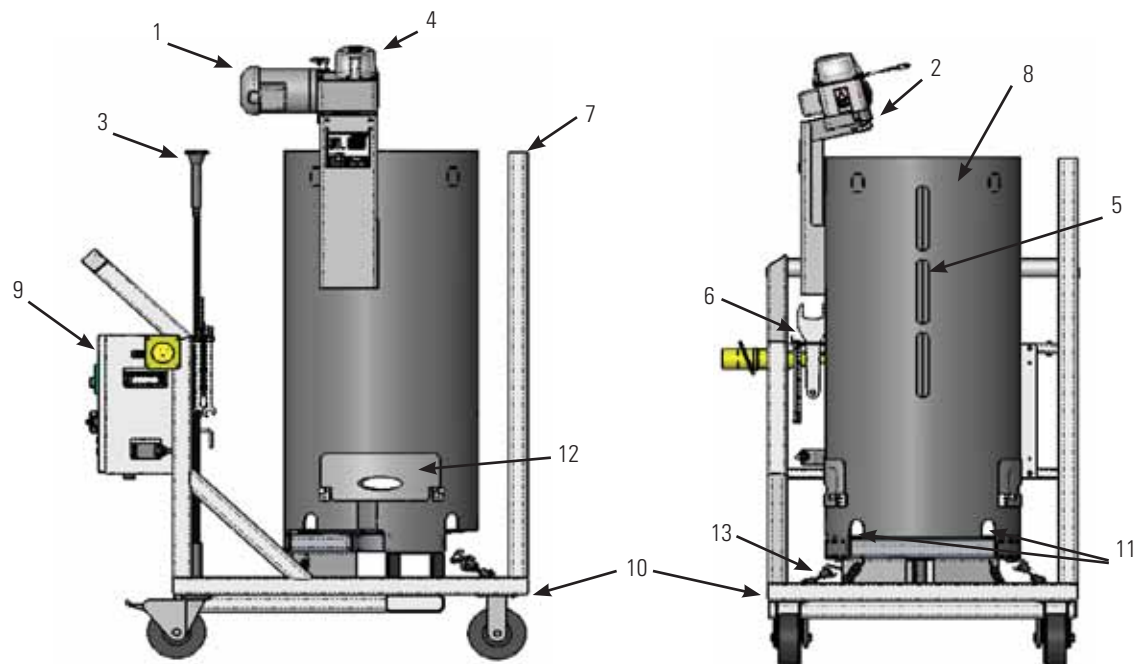
Outer Packaging	Supplied 'flat-packed' Two polyethylene outer layers
Label	Description Product code Lot number Expiry date on outer packaging and shipping container
Sterilization	Irradiation (25 to 38 kGy) inside outer packaging
Shipping Container	Durable cardboard carton
Documentation	Certificate of Analysis provided with each lot for each delivery

Hardware Features

200 L S.U.M.:

The stainless steel outer support container contains the following features:

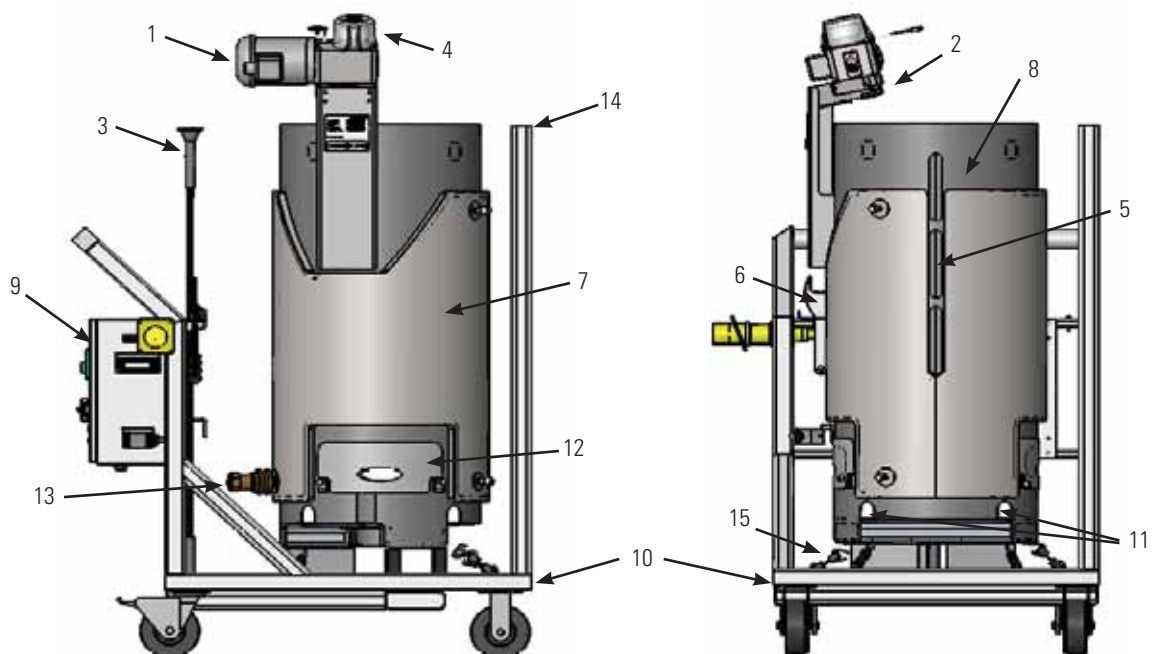
- | | | |
|-------------------------------------|--|---------------------------------------|
| 1. Mixer motor | 6. Standard tool set | 11. Bottom cut outs for BPC alignment |
| 2. Bearing port receiver with clamp | 7. Powdertainer Hanger Mount | 12. Probe Access Door |
| 3. Drive shaft | 8. Stainless steel (304) outer support container | 13. Stretch Hooks |
| 4. Mixing assembly with shield | 9. Control panel | |
| 5. Liquid sight window | 10. Platform with large diameter wheels | |



200 L with Water Jacket:

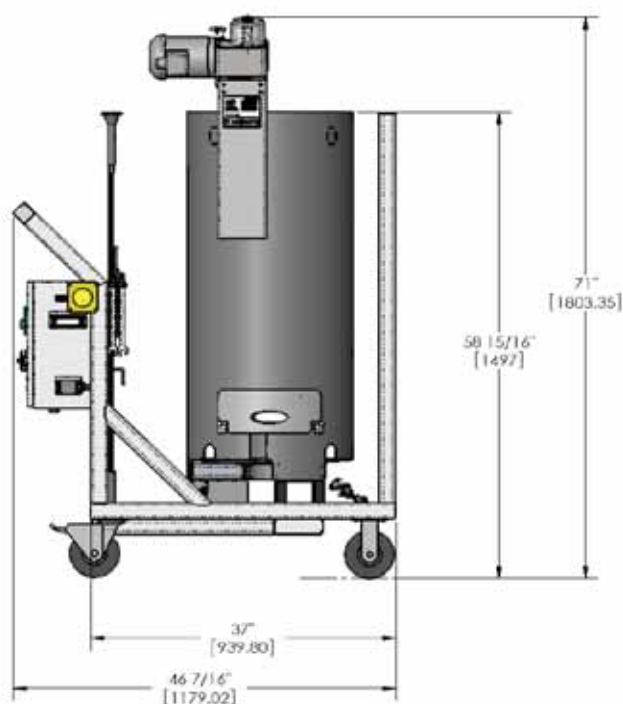
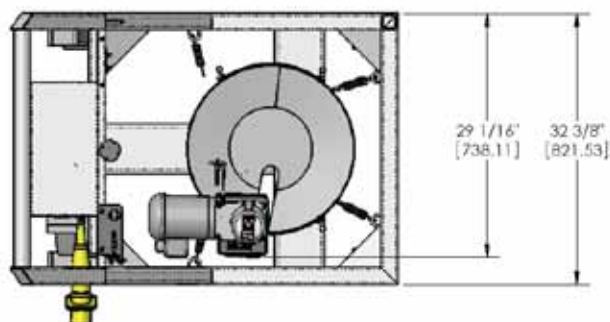
The stainless steel outer support container contains the following features:

- | | | |
|-------------------------------------|--|------------------------------------|
| 1. Mixer motor | 7. Water Jacket | 13. Jacket quick connect couplings |
| 2. Bearing port receiver with clamp | 8. Stainless steel (304) outer support container | 14. Powdertainer Hanger Mount |
| 3. Drive shaft | 9. Control panel | 15. Stretch Hooks |
| 4. Mixing assembly with shield | 10. Platform with large diameter wheels | |
| 5. Liquid sight window | 11. Bottom cut outs for BPC alignment | |
| 6. Standard tool set | 12. Probe access door | |

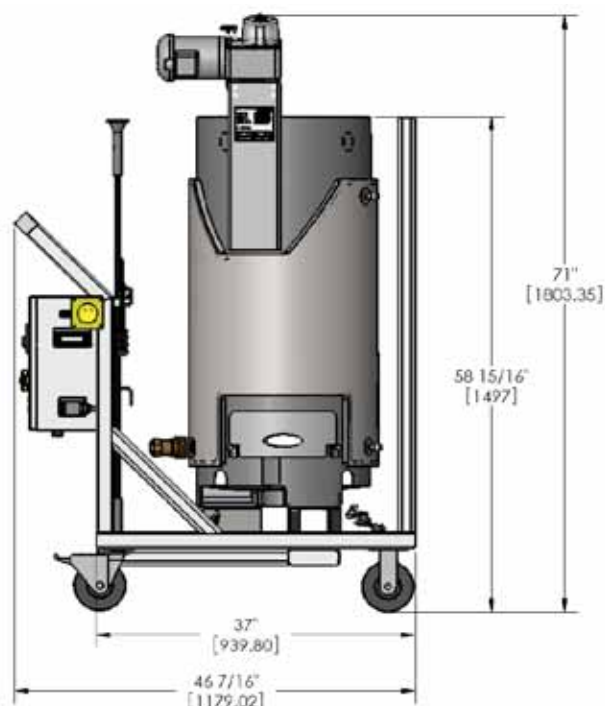
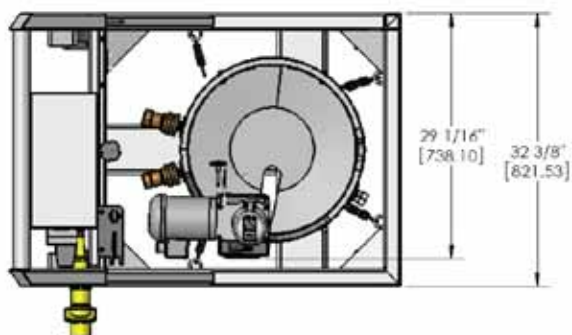


Outer Support Container (units in inches [mm])

200 L S.U.M.:



200 L S.U.M. Jacket:



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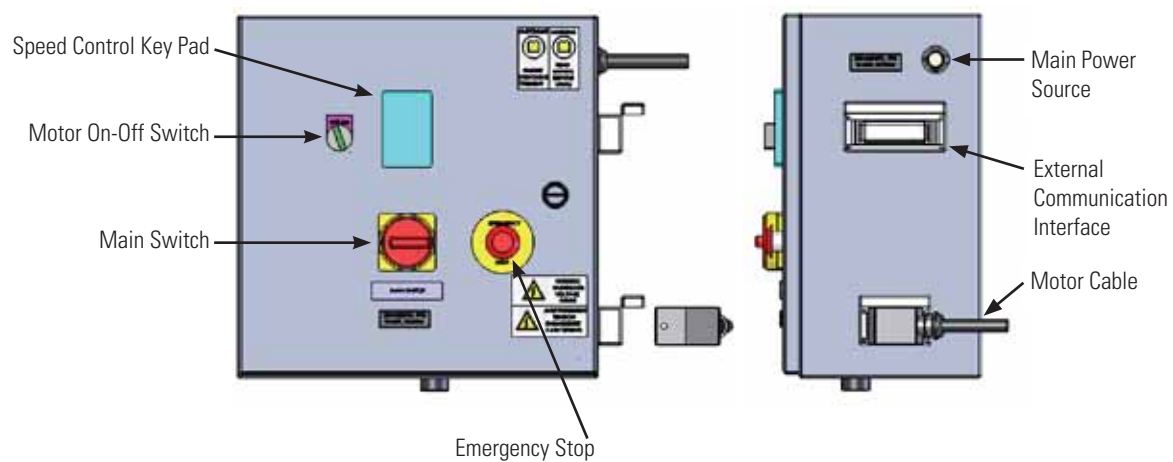
3.2.2 200 L Hardware Specifications Non-Heated

Vessel Geometry	Rated Liquid Working Volume	200 L
	Minimum Liquid Working Volume	40 L
	BPC Chamber Diameter	20" (50.8 cm)
	BPC Chamber Shoulder Height	48.6" (123.4 cm)
	Liquid Height @ Rated Working Volume	39" (99 cm)
	Fluid Geometry @ Working Volume (height/diameter) Ratio	1.95:1
	Overall Geometry (height/diameter) Ratio	2.2:1
	Hold up volume (typical)	<50 mL
Impeller	Impeller (quantity X blade count)	1 x 3
	Impeller Blade Pitch (angle)	45°
	Impeller Diameter	7.875" (20 cm)
Mixing	Maximum Mixing Rate (revolutions per minute)	350 rpm
	Overall Drive Shaft Length	51" (129.5 cm)
Drive Motor	Programmable VFD, Remote Panel Interface	standard
	Mixer Motor Drive (voltage, phase, amp)	208 VAC, three, 15 Amp
	Motor Power Rating	0.5 hp (372.8 W)
	Motor Torque Rating	80 lb _f -in (9.04 Nm)
	Gear Reduction	5:1
Support Container	Primary Construction Material (Outer Support Container)	304 Stainless Steel
	Primary Construction Material (Inner Support Tank)	304 Stainless Steel
	Skid Width	32.5" (82.6 cm)
	Skid Depth	47" (119.4 cm)
	Skid Height	71" (180 cm)
	Dry Skid Weight (mass)	500 lb (227 kg)
	Wet Skid Weight - Rated Working Volume (mass)	1009 lbs (458 kg)
General	Minimum Ceiling Height Recommendations	10' (305 cm)
	Electrical Power Supply Requirement (voltage, phase, amp)	120 or 240 VAC, single, 15 Amp Non GFCI circuit
	Electrical Class Ratings	ETL, CE, IP-56
	Contact Materials Biocompatibility	USP Class VI
	Validated System Reliability (minimum)	0.9 @ 90%
	Weigh Scale Platform Area (minimum area for caster stands)	36" x 36" (92 cm x 92 cm)

3.2.3 200 L Hardware Specifications Water Jacket

Vessel Geometry	Rated Liquid Working Volume	200 L
	Minimum Liquid Working Volume	40 L
	BPC Chamber Diameter	20" (50.8 cm)
	BPC Chamber Shoulder Height	48.6" (123.4 cm)
	Liquid Height @ Rated Working Volume	39" (99 cm)
	Fluid Geometry @ Working Volume (height/diameter) Ratio	1.95:1
	Overall Geometry (height/diameter) Ratio	2.2:1
	Hold up volume (typical)	<50 mL
Impeller	Impeller (quantity X blade count)	1 x 3
	Impeller Blade Pitch (angle)	45°
	Impeller Diameter	7.875" (20 cm)
Mixing	Maximum Mixing Rate (revolutions per minute)	350 rpm
	Overall Drive Shaft Length	51" (129.5 cm)
Drive Motor	Programmable VFD, Remote Panel Interface	standard
	Mixer Motor Drive (voltage, phase, amp)	208 VAC, three, 15 Amp
	Motor Power Rating	0.5 hp (372.8 W)
	Motor Torque Rating	80 lb _f -in (9.04 Nm)
	Gear Reduction	5:1
Support Container	Primary Construction Material (Outer Support Container)	304 Stainless Steel
	Primary Construction Material (Inner Support Tank)	304 Stainless Steel
	Skid Width	32.5" (82.6 cm)
	Skid Depth	47" (119.4 cm)
	Skid Height	71" (180 cm)
	Dry Skid Weight (mass)	558 lb (253 kg)
	Wet Skid Weight - Rated Working Volume (mass)	1009 lbs (458 kg)
General	Minimum Ceiling Height Recommendations	10' (305 cm)
	Electrical Power Supply Requirement (voltage, phase, amp)	120 or 240 VAC, single, 15 Amp Non GFCI circuit
	Electrical Class Ratings	ETL, CE, IP-56
	Contact Materials Biocompatibility	USP Class VI
	Validated System Reliability (minimum)	0.9 @ 90%
	Weigh Scale Platform Area (minimum area for caster stands)	36" x 36" (92 cm x 92 cm)

3.2.4 200 L Control Panel Layout



3.3 500 L Single-Use Mixer

- 3.3.1 500 L S.U.M. Data Sheet
- 3.3.2 500 L S.U.M. Hardware Specifications - Non-Heated
- 3.3.3 500 L S.U.M. Hardware Specifications - Water Jacket
- 3.3.4 500 L Control Panel Layout

Thermo Scientific HyClone Single-Use Mixer (S.U.M.) 500 L

The Thermo Scientific HyClone Single-Use Mixer (S.U.M.) is part of a product family which provides efficient and powerful mixing for a wide range of applications based on a conventional stirred tank design. For use with powder hydration for preparation of critical sterile and non-sterile solutions and suspensions.

The current range includes units with maximum volumes of 50, 200, 500, 1000 and 2000 L.

Overview:

The Single-Use Mixer is based on the same concept as the Thermo Scientific HyClone Single-Use Bioreactor (S.U.B.) with a single-use BioProcess Container (BPC®), an integrated impeller and a reusable hardware system providing support, mobility, mixing motor and control system.

The range of product solutions included in this data sheet expand the functionality offered by the original S.U.M. products described in data sheet 033.

These offerings include:

Stainless Steel Hardware Systems

- With or without heating/cooling jacket
- Cutout sections to facilitate S.U.M. BPC loading and monitoring probe capability
- Location mechanism for S.U.M. BPC

S.U.M. BPC Options

- Open top liner media/buffer preparation
- Closed BPC with powder port for contained media/buffer preparation

- Closed BPC with powder port and monitoring probe capability
- Closed BPC for liquid-liquid mixing of critical sterile solutions such as pooling of fractions or processing intermediate solutions
- Closed BPC for liquid-liquid mixing with monitoring probe capability



500 L S.U.M.

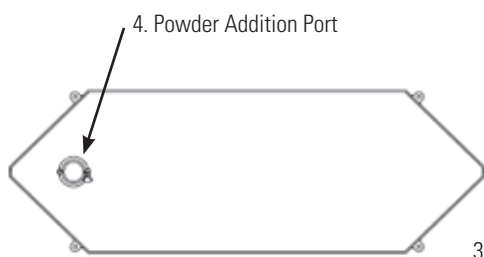
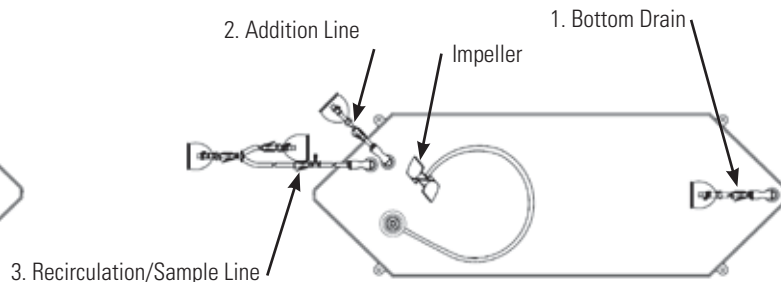
Item	500 L Non-Heated	500 L Water Jacket Heater
Rated Liquid Working Volume	500 L	
Minimum Liquid Working Volume	100 L	
BPC Chamber Diameter	29.75" (75.6 cm)	
BPC Chamber Shoulder Height	57.5" (146 cm)	
Liquid Height @ Rated Working Volume	44" (111.852.1 cm)	
Overall Geometry (height/diameter ratio)	1.5:1	
Fluid Geometry @ Working Volume (height/diameter) Ratio	1.7:1	
Impeller (quantity x blade count)	1 x 3	
Impeller Diameter	7.875" (20 cm)	
Hold-Up Volume (typical)	<100 mL	
Electrical Power Supply Requirement (voltage, phase, amp)	120 VAC, single, 15 Amp—Non GFCI circuit and 240 VAC, single, 15 Amp—Non GFCI circuit	
Skid Width	33.6" (85.3 cm)	
Skid Depth	52" (132 cm)	
Skid Height	77" (195.6 cm)	
Dry Skid Weight (mass)	707 lbs (321 kg)	734 lbs (333 kg)
Wet Skid Weight—Rated Working Volume (mass)	1809 lbs (821 kg)	1836 lbs (833 kg)
Minimum Ceiling Height Requirement	11' (335 cm)	
S.U.M. Recommended Operating Parameters		
Temperature	2-40°C	
Motor Speed	0-350 rpm	
Volume Range	20-100% of Nominal	
Maximum Closed Top Mixing Bag Pressure	.2 psig	
Continuous Operating Time	21 days*	

*Mixing time at nominal volume only.

Standard BPC Configurations (CX5-14 Film)

Powder-Liquid Applications—Part number SH30751.01

For use with tubing welder and with CPC® Quick Connects

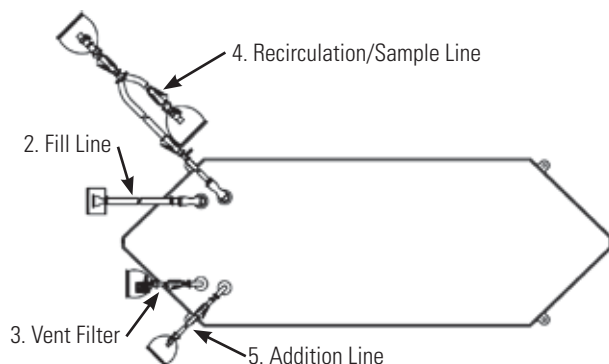
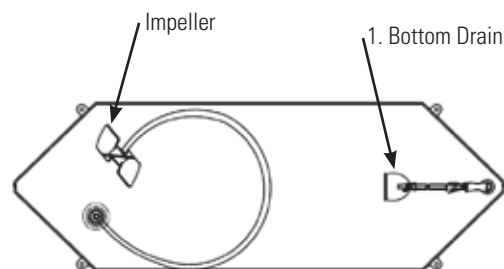
Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex® X 48" (122 cm)	Capped 1/2" (12.7 mm) MPX insert
2	Addition Line	1/2" (12.7 mm) ID X 5/8" (15.9 mm) OD C-Flex X 60" (152 cm)	Plugged 1/2" (12.7 mm) MPX body
3	Recirculation/Sample Line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 66" (168 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
4	Powder Addition Port	3" (76 mm) Sanitary Fitting, Tri-clamp	Cap with gasket

Standard BPC Configurations (CX5-14 Film)

Liquid-Liquid Applications—Part number SH30754.01

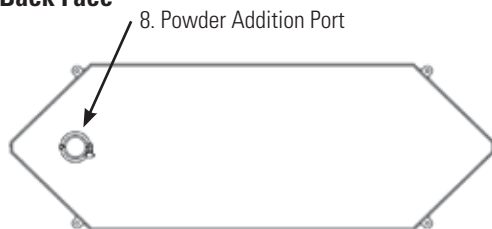
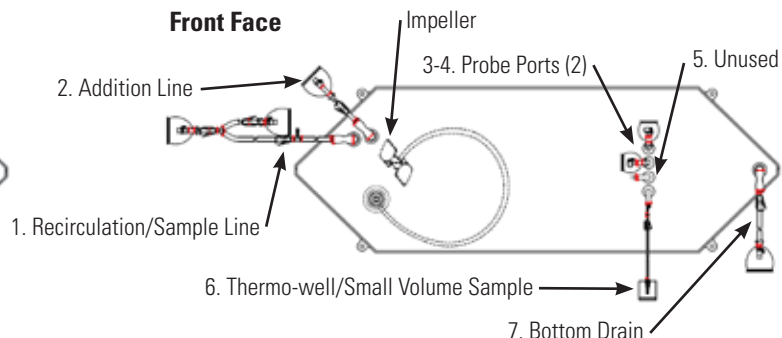
For use with tubing welder and with CPC® Quick Connects

Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Capped 1/2" (12.7 mm) MPX insert
2	Fill Line	3/4" (19.1 mm) ID X 1" (25.4 mm) OD C-Flex X 60" (152 cm)	1 1/2" (38.1 mm) Tri-clamp SterilEnz™
3	Vent Filter	1/4" (6.4 mm) ID X 1/2" (12.7 mm) OD C-Flex X 4" (10.2 cm)	Sterile Hydrophobic Vent Filter (0.2 micron PVDF - Pall Acro 50)
4	Recirculation/Sample Line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 66" (168 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
5	Addition Line	3/8" (9.5 mm) ID X 5/8" (15.9 mm) OD C-Flex X 24" (61 cm)	Plugged 3/8" (9.5 mm) MPX body

Standard BPC Configurations (CX5-14 Film)

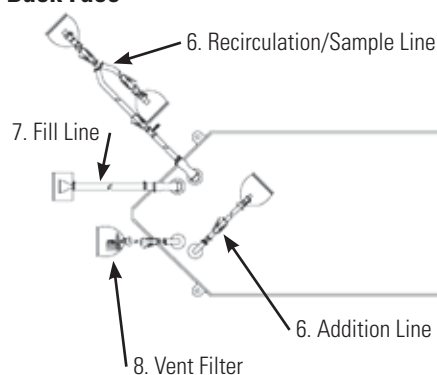
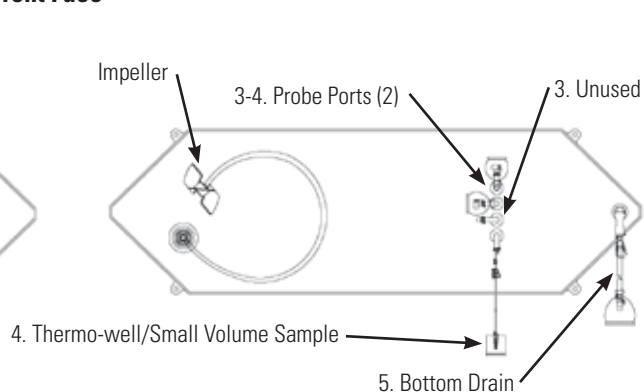
Powder-Liquid Applications with Probe Ports and Thermo-well—Part number SH30751.02
For use with tubing welder and with CPC® Quick Connects

Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Recirculation/Sample line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 66" (168 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
2	Addition Line	1/2" (12.7 mm) ID X 5/8" (15.9 mm) OD C-Flex X 60" (152 cm)	Plugged 1/2" (12.7 mm) MPX body
3-4	Probe Ports (2)	None	Pall™ Kleenpak™ Aseptic Connector KPCHT Series (Female)
5	Unused	None	Plug
6	Thermo-well/ Small Volume Sample	Thermo-well Adapter for 1/8" (3.2 mm) Diameter 1/8" (3.2 mm) ID X 1/4" (6.4 mm) OD C-Flex X 12" (30 cm)	Luer and SmartSite® Valve Port
7	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Plugged 1/2" (12.7 mm) MPX body
8	Powder Addition Port	3" (76 mm) Sanitary Fitting, Tri-clamp	Cap with gasket

Standard BPC Configurations (CX5-14 Film)

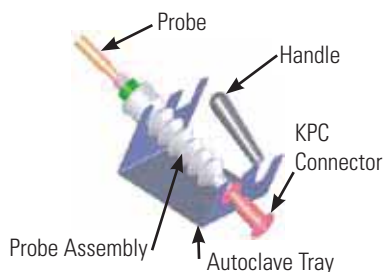
Liquid-Liquid Applications with Probe Ports and Thermo-well—Part number SH30754.02
For use with tubing welder and with CPC® Quick Connects

Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1-2	Probe Ports (2)	None	Pall Kleenpak Aseptic Connector KPCHT Series (Female)
3	Unused	None	Plug
4	Thermo-well/ Small Volume Sample	Thermo-well Adapter for 1/8" (3.2 mm) Diameter 1/8" (3.2 mm) ID X 1/4" (6.4 mm) OD C-Flex X 12" (30 cm)	Luer and SmartSite Valve Port
5	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Capped 1/2" (1.27 cm) MPX insert
6	Recirculation/Sample line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 66" (168 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
7	Fill Line	3/4" (19.1 mm) ID X 1" (25.4 mm) OD C-Flex X 60" (152 cm)	1 1/2" Tri-clamp SterilEnz
8	Vent Filter	1/4" (6.4 mm) ID X 1/2" (12.7 mm) OD C-Flex X 4" (10.2 cm)	Sterile Hydrophobic Vent Filter (0.2 micron PVDF - Pall Acro 50)
9	Addition Line	3/8" (9.5 mm) ID X 5/8" (15.9 mm) OD C-Flex X 24" (61 cm)	Plugged 3/8" (9.5 mm) MPX body

Ordering Information for Standard Products

Autoclave Tray and Probe Kits:

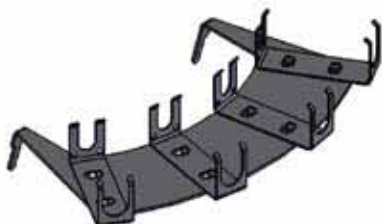


Additional Information on Autoclave Tray:

- Fabricated from stainless steel
- Plastic carry handle for easy transport right out of the autoclave
- Positions probes on 15% incline for greater probe/membrane longevity
- Will restrain probe bellows from collapsing during sterilization
- Probe holder accommodates two probes

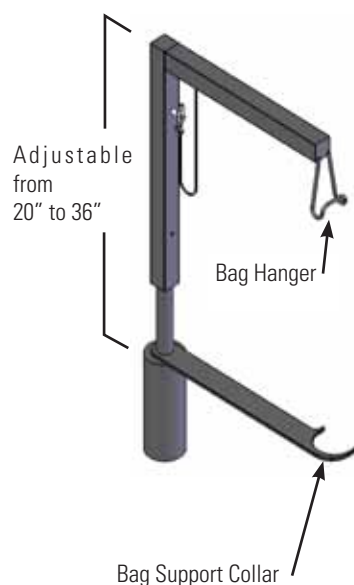
Probe Shelf:

The S.U.M. can be equipped with a probe shelf for probe support and retention.



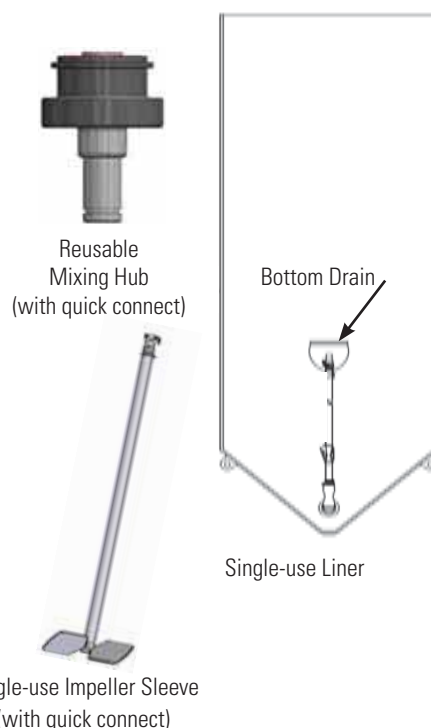
Powdertainer Hanger:

The Single-Use Mixer (S.U.M.) can be equipped with a Thermo Scientific HyClone Powdertainer hanger if so desired. When adding solids to liquids, this optional feature enables utilization of the Powdertainer powder feed system. The Powdertainer hanger can be used to support full 1, 5 or 25 Kg Powdertainers and positions the 3" sanitary connectors for bag to bag connection and solids transfer.



Open-Top Mixing (OTM) use:

The S.U.M. can be equipped with a reusable mixing hub accessory to enable use of open top liners and single-use impeller sleeves. The OTM option is a non-sterile easy-to-use mixing option. The reusable hub is simply placed into the motor's bearing port receiver and latched into place. The single-use impeller sleeve attaches to the hub's quick connect end. With an open liner in position and a drive shaft inserted the system is ready to use.



Accessories:

Part Number	Description	
SH30720.01	Probe Assembly (non-sterile)	Used to package probes (not supplied) for sterilization and to aseptically connect them to the S.U.M. BPC.
SV20664.01	Heavy Duty Tubing Clamp	Reusable tubing clamp used on probe ports when connecting probe assembly.
SV20664.02	Heavy Duty Tubing Clamp (4 pack of SV20664.01)	
SV20664.03	Heavy Duty Tubing Clamp (10 pack of SV20664.01)	
SV20750.01	S.U.M. thermo-well/sample port	Used for RTD calibration/validation.
SV20778.01	RTD	Pt100 Resistance Temperature Detector for use with S.U.M BPC thermo-well/sampling port.
SV50177.01	Autoclave Tray for Probe Kits (stainless steel)	Support tray which allows the probes to be safely autoclaved.
SH30845.01	Sterile Sampling Manifold with luer lock (individual)	Available for aseptic luer connection or welding onto the sample line to take sample sets.
SH30845.02	Sterile Sampling Manifold with luer lock (10 pack)	
SV50218	Load Cells*	Installed by manufacturer or end-user
SV50177.94	Probe Shelf	Support shelf for use with probe assemblies.
SV50187.01	Powdertainer Hanger with Support Collar	To support BPCs during Powdertainer attachment
SV50177.77	Reusable Mixing Hub	Required for use with single-use impeller sleeve
SH30762.02	Single-use Liner	Bottom drain liner with 72" (182.9 cm) of ½" (12.7 mm) C-Flex tubing and an MPX insert connector, CX3-9 Film
SH30749.10	Single-use Impeller Sleeve	For Open-Top Mixing

* For more information on Load Cell options refer to Data Sheet 048.

Hardware Standard Products

Non-Heated:

Part Number	Description	
SV50214.01	500 L S.U.M., 120 VAC, Single Phase	Includes: 304 stainless steel outer support container with swivel caster platform, variable speed agitation controller, motor, drive assembly with shaft and standard tool set
SV50214.02	500 L S.U.M., 240 VAC, Single Phase	

Water Jacket:

Part Number	Description	
SV50214.03	500 L S.U.M., 120 VAC, Single Phase	Includes: 304 stainless steel outer support container with swivel caster platform, variable speed agitation controller, motor, drive assembly with shaft, integrated water jacket and standard tool set
SV50214.04	500 L S.U.M., 240 VAC, Single Phase	

Custom BPC Options:

Tubing Type	C-Flex (clear, white, and ADCF), Silicone, PVC, PharMed® or PharmaPure®
Tubing Size	Specific Lengths of 1/8 to 1" (3.18 to 25.4 mm) ID — depending on type of tubing chosen
Connectors	Luer — 1/8 to 1/2" (3.18 to 12.7 mm) ID CPC — 1/4 to 3/4" (6.35 to 19 mm) ID SIP Connector — 1/4 to 3/4" (6.35 to 19 mm) ID Tri-clamp — 1/8" to 1" (3.18 to 25.4mm) ID Mini-Tri-clamp — 1/8 to 1/2" (6.35 to 12.7 mm) ID Aseptic Connection Device — All available sizes of Pall Kleenpak and BioQuate™ DAC
Others	Needle-free sample port (SmartSite or Clave®) Filter Capsule (Millipore®, Pall, Sartorius™, Domnick Hunter®, Meissner®, Other)

Please Note: Not all options are available for all ports. Customization of port type and location, chamber dimensions or mixing assembly is not available. For additional information, please refer to the Selection Guides in the 2008 BPC Catalog.

Presentation (as dry BPC systems):

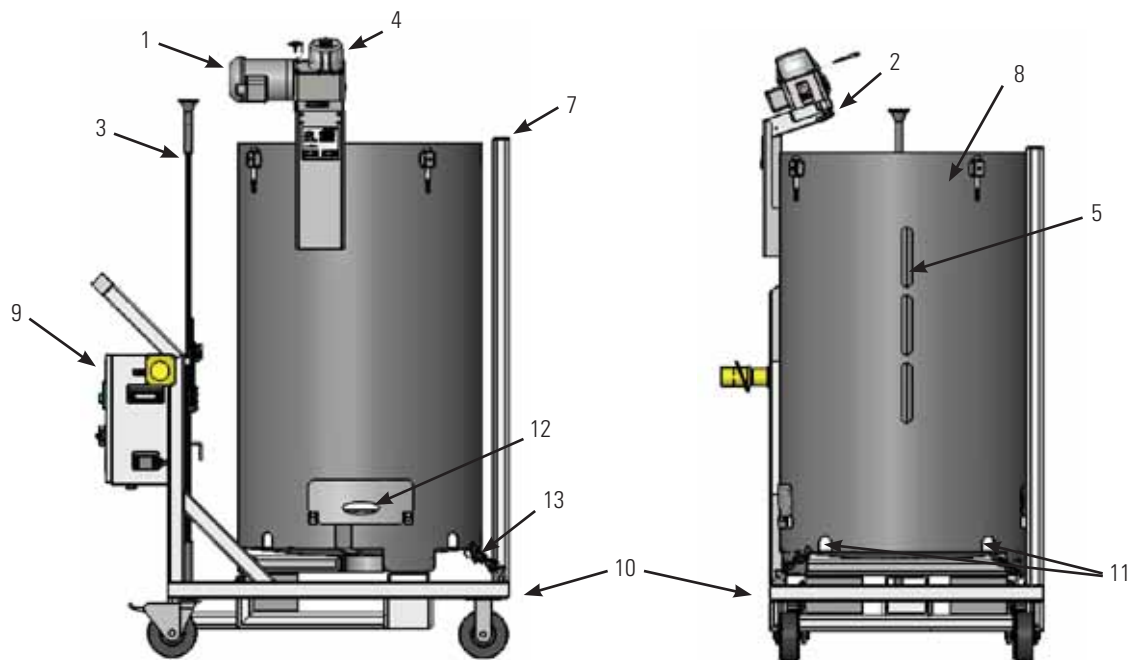
Outer Packaging	Supplied 'flat-packed' Two polyethylene outer layers
Label	Description Product code Lot number Expiry date on outer packaging and shipping container
Sterilization	Irradiation (25 to 38 kGy) inside outer packaging
Shipping Container	Durable cardboard carton
Documentation	Certificate of Analysis provided with each lot for each delivery

Hardware Features

500 L S.U.M.:

The stainless steel outer support container contains the following features:

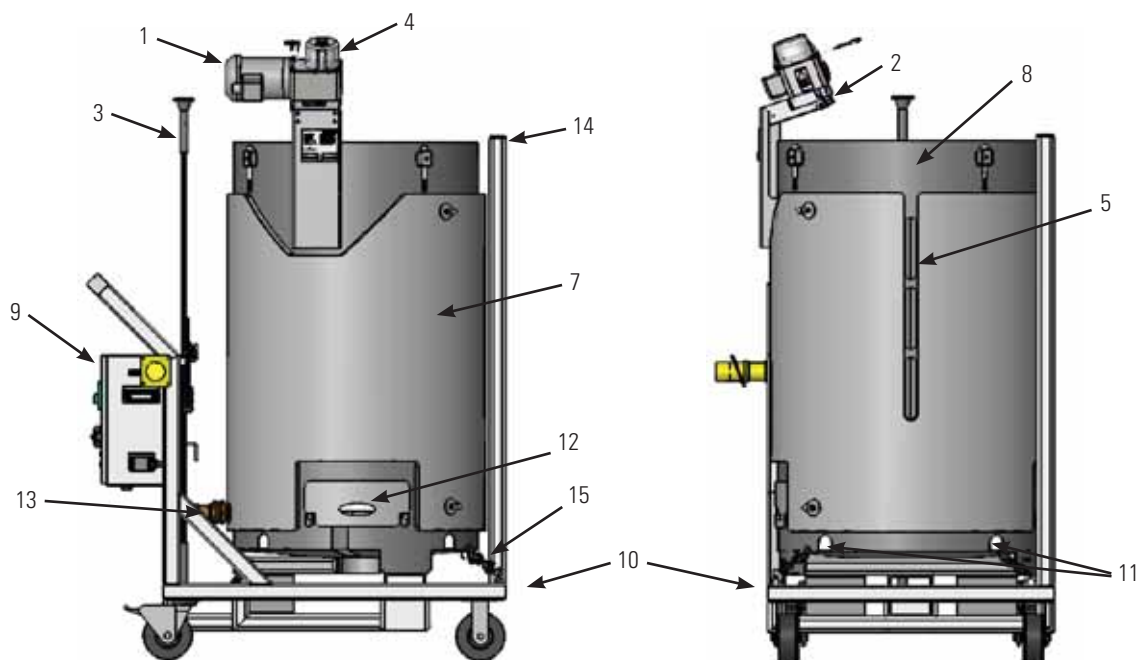
- | | | |
|-------------------------------------|--|---------------------------------------|
| 1. Mixer motor | 6. Standard tool set (not shown) | 11. Bottom cut outs for BPC alignment |
| 2. Bearing port receiver with clamp | 7. Powdertainer Hanger Mount | 12. Probe Access Door |
| 3. Drive shaft | 8. Stainless steel (304) outer support container | 13. Stretch Hooks |
| 4. Mixing assembly with shield | 9. Control panel | |
| 5. Liquid sight window | 10. Platform with large diameter wheels | |



500 L with Water Jacket:

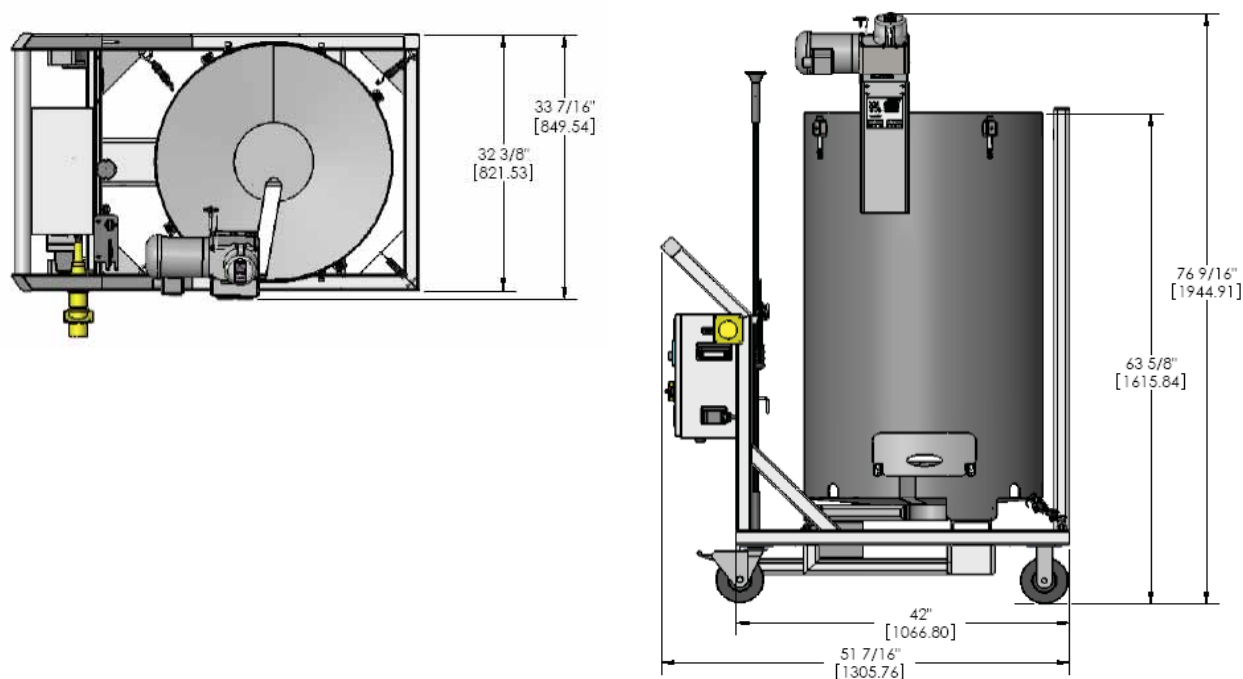
The stainless steel outer support container contains the following features:

- | | | |
|-------------------------------------|--|---------------------------------------|
| 1. Mixer motor | 6. Standard tool set (not shown) | 11. Bottom cut outs for BPC alignment |
| 2. Bearing port receiver with clamp | 7. Water Jacket | 12. Probe access door |
| 3. Drive shaft | 8. Stainless steel (304) outer support container | 13. Jacket quick connect couplings |
| 4. Mixing assembly with shield | 9. Control panel | 14. Powdertainer Hanger Mount |
| 5. Liquid sight window | 10. Platform with large diameter wheels | 15. Stretch Hooks |

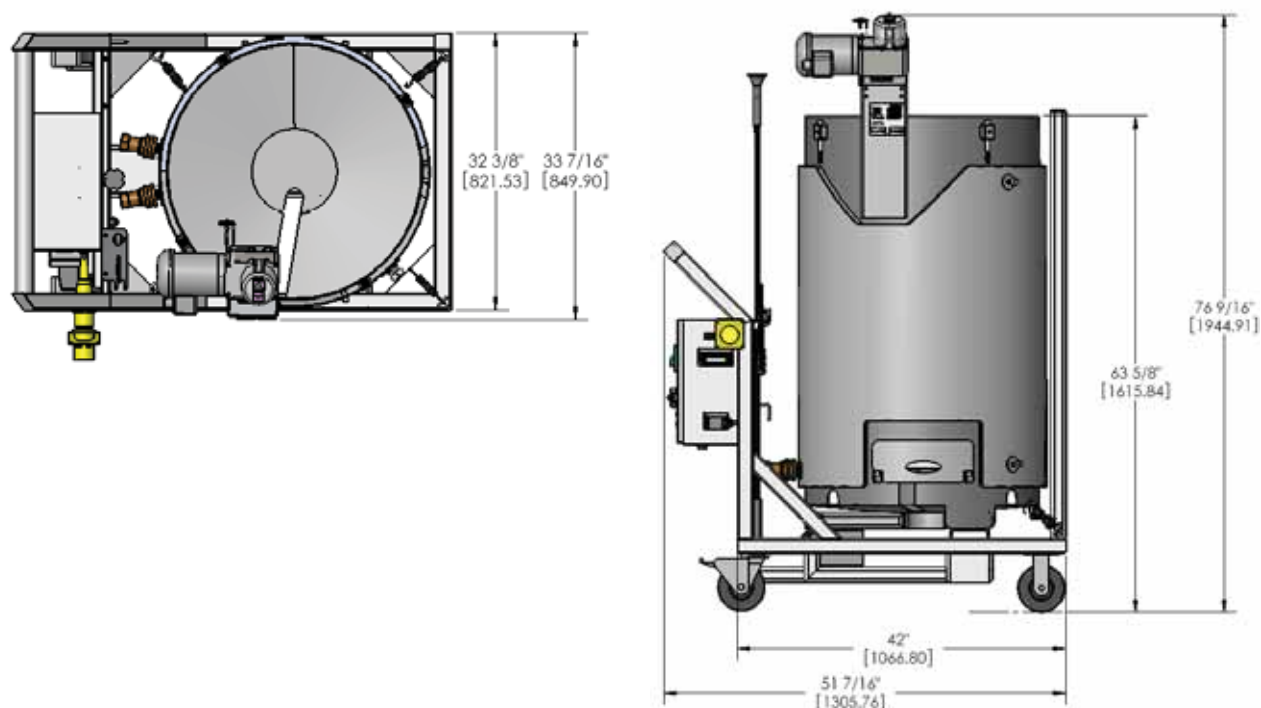


Outer Support Container (units in inches [mm])

500 L S.U.M.:



500 L S.U.M. Jacket:



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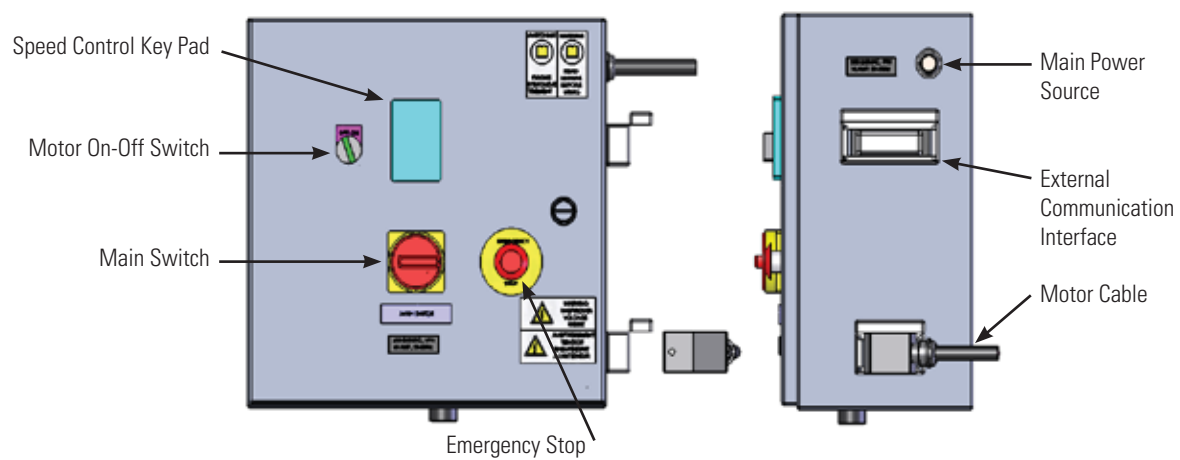
3.3.2 500 L Hardware Specifications Non-Heated

Vessel Geometry	Rated Liquid Working Volume	500 L
	Minimum Liquid Working Volume	100 L
	BPC Chamber Diameter	29.75" (75.6 cm)
	BPC Chamber Shoulder Height	57.5" (146 cm)
	Liquid Height @ Rated Working Volume	44" (111.8 cm)
	Fluid Geometry @ Working Volume (height/diameter) Ratio	1.5:1
	Overall Geometry (height/diameter) Ratio	1.7:1
	Hold up volume (typical)	<100 mL
Impeller	Impeller (quantity X blade count)	1 x 3
	Impeller Blade Pitch (angle)	45°
	Impeller Diameter	7.875" (20 cm)
Mixing	Maximum Mixing Rate (revolutions per minute)	350 rpm
	Overall Drive Shaft Length	60" (152.4 cm)
Drive Motor	Programmable VFD, Remote Panel Interface	standard
	Mixer Motor Drive (voltage, phase, amp)	208 VAC, three, 15 Amp
	Motor Power Rating	0.5 hp (372.8 W)
	Motor Torque Rating	80 lb _f -in (9.04 Nm)
	Gear Reduction	5:1
Support Container	Primary Construction Material (Outer Support Container)	304 Stainless Steel
	Primary Construction Material (Inner Support Tank)	304 Stainless Steel
	Skid Width	33.6" (85.3 cm)
	Skid Depth	52" (132 cm)
	Skid Height	77" (195.6 cm)
	Dry Skid Weight (mass)	547 lb (248 kg)
	Wet Skid Weight - Rated Working Volume (mass)	1771 lbs (803 kg)
General	Minimum Ceiling Height Recommendations	11' (335 cm)
	Electrical Power Supply Requirement (voltage, phase, amp)	120 or 240 VAC, single, 15 Amp Non GFCI circuit
	Electrical Class Ratings	ETL, CE, IP-56
	Contact Materials Biocompatibility	USP Class VI
	Validated System Reliability (minimum)	0.9 @ 90%
	Weigh Scale Platform Area (minimum area for caster stands)	42" x 42" (107 cm x 107 cm)

3.3.3 500 L Hardware Specifications Water Jacket

Vessel Geometry	Rated Liquid Working Volume	500 L
	Minimum Liquid Working Volume	100 L
	BPC Chamber Diameter	29.75" (75.6 cm)
	BPC Chamber Shoulder Height	57.5" (146 cm)
	Liquid Height @ Rated Working Volume	44" (111.8 cm)
	Fluid Geometry @ Working Volume (height/diameter) Ratio	1.5:1
	Overall Geometry (height/diameter) Ratio	1.7:1
	Hold up volume (typical)	<100 mL
Impeller	Impeller (quantity X blade count)	1 x 3
	Impeller Blade Pitch (angle)	45°
	Impeller Diameter	7.875" (20 cm)
Mixing	Maximum Mixing Rate (revolutions per minute)	350 rpm
	Overall Drive Shaft Length	60" (152.4 cm)
Drive Motor	Programmable VFD, Remote Panel Interface	standard
	Mixer Motor Drive (voltage, phase, amp)	208 VAC, three, 15 Amp
	Motor Power Rating	0.5 hp (372.8 W)
	Motor Torque Rating	80 lb _f -in (9.04 Nm)
	Gear Reduction	5:1
Support Container	Primary Construction Material (Outer Support Container)	304 Stainless Steel
	Primary Construction Material (Inner Support Tank)	304 Stainless Steel
	Skid Width	33.6" (85.3 cm)
	Skid Depth	52" (132 cm)
	Skid Height	77" (195.6 cm)
	Dry Skid Weight (mass)	654 lb (297 kg)
	Wet Skid Weight - Rated Working Volume (mass)	1771 lbs (803 kg)
General	Minimum Ceiling Height Recommendations	11' (335 cm)
	Electrical Power Supply Requirement (voltage, phase, amp)	120 or 240 VAC, single, 15 Amp Non GFCI circuit
	Electrical Class Ratings	ETL, CE, IP-56
	Contact Materials Biocompatibility	USP Class VI
	Validated System Reliability (minimum)	0.9 @ 90%
	Weigh Scale Platform Area (minimum area for caster stands)	42" x 42" (107 cm x 107 cm)

3.3.4 500 L Control Panel Layout



3.4 1000 L Single-Use Mixer

- 3.4.1 1000 L S.U.M. Data Sheet
- 3.4.2 1000 L S.U.M. Hardware Specifications - Non-Heated
- 3.4.3 1000 L S.U.M. Hardware Specifications - Water Jacket
- 3.4.4 1000 L Control Panel Layout

Thermo Scientific HyClone Single-Use Mixer (S.U.M.) 1000 L

The Thermo Scientific HyClone Single-Use Mixer (S.U.M.) is part of a product family which provides efficient and powerful mixing for a wide range of applications based on a conventional stirred tank design. For use with powder hydration for preparation of critical sterile and non-sterile solutions and suspensions.

The current range includes units with maximum volumes of 50, 200, 500, 1000 and 2000 L.

Overview:

The Single-Use Mixer is based on the same concept as the Thermo Scientific HyClone Single-Use Bioreactor (S.U.B.) with a single-use BioProcess Container (BPC®), an integrated impeller and a reusable hardware system providing support, mobility, mixing motor and control system.

The range of product solutions included in this data sheet expand the functionality offered by the original S.U.M. products described in data sheet 033.

These offerings include:

Stainless Steel Hardware Systems

- With or without heating/cooling jacket
- Cutout sections to facilitate S.U.M. BPC loading and monitoring probe capability
- Location mechanism for S.U.M. BPC

S.U.M. BPC Options

- Open top liner media/buffer preparation
- Closed BPC with powder port for contained media/buffer preparation

- Closed BPC with powder port and monitoring probe capability
- Closed BPC for liquid-liquid mixing of critical sterile solutions such as pooling of fractions or processing intermediate solutions
- Closed BPC for liquid-liquid mixing with monitoring probe capability



1000 L S.U.M.

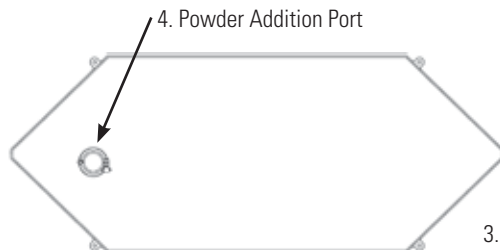
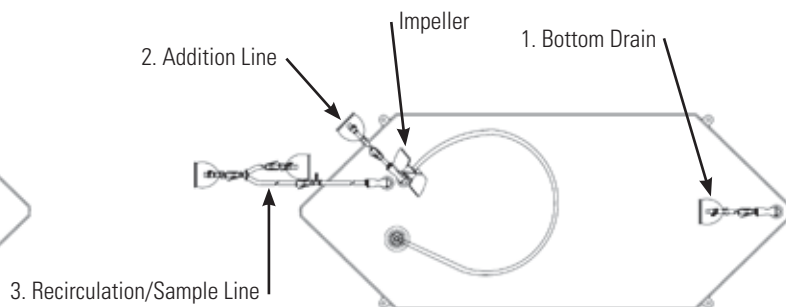
Item	1000 L Non-Heated	1000 L Water Jacket Heater
Rated Liquid Working Volume	1000 L	
Minimum Liquid Working Volume	200 L	
BPC Chamber Diameter	41.5" (105.4 cm)	
BPC Chamber Shoulder Height	61.9" (157.2 cm)	
Liquid Height @ Rated Working Volume	45.5" (115.6 cm)	
Overall Geometry (height/diameter ratio)	1.1:1	
Fluid Geometry @ Working Volume (height/diameter) Ratio	1.2:1	
Impeller (quantity x blade count)	1 x 3	
Impeller Diameter	7.875" (20 cm)	
Hold-Up Volume (typical)	<300 mL	
Electrical Power Supply Requirement (voltage, phase, amp)	120 VAC, single, 15 Amp—Non GFCI circuit and 240 VAC, single, 15 Amp—Non GFCI circuit	
Skid Width	44.5" (113 cm)	
Skid Depth	59" (150 cm)	
Skid Height	78" (198 cm)	
Dry Skid Weight (mass)	950 lbs (431 kg)	983 lbs (446 kg)
Wet Skid Weight—Rated Working Volume (mass)	3154 lbs (1431 kg)	3187 lbs (1446 kg)
Minimum Ceiling Height Requirement	11' (335 cm)	
S.U.M. Recommended Operating Parameters		
Temperature	2-40°C	
Motor Speed	0-350 rpm	
Volume Range	20-100% of Nominal	
Maximum Closed Top Mixing Bag Pressure	.2 psig	
Continuous Operating Time	21 days*	

*Mixing time at nominal volume only.

Standard BPC Configurations (CX5-14 Film)

Powder-Liquid Applications—Part number SH30752.01

For use with tubing welder and with CPC® Quick Connects

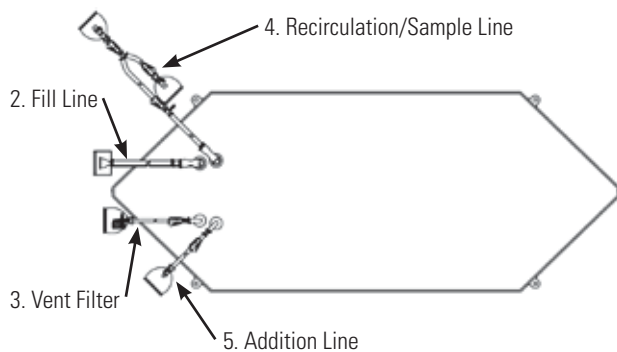
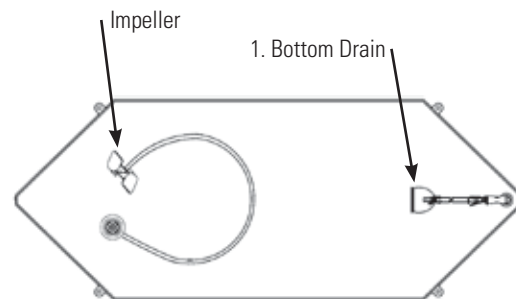
Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex® X 48" (122 cm)	Capped 1/2" (12.7 mm) MPX insert
2	Addition Line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 72" (183 cm)	Plugged 1/2" (12.7 mm) MPX body
3	Recirculation/Sample line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 78" (198 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
4	Powder Addition Port	3" (76 mm) Sanitary Fitting, Tri-clamp	Cap with gasket

Standard BPC Configurations (CX5-14 Film)

Liquid-Liquid Applications—Part number SH30755.01

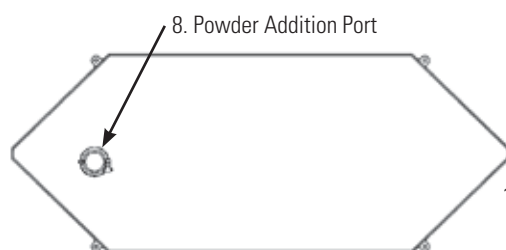
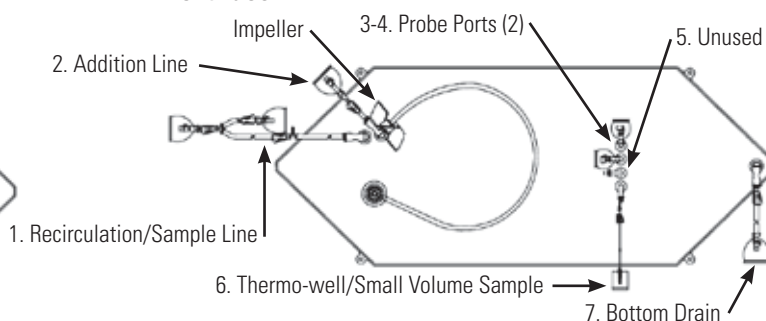
For use with tubing welder and with CPC® Quick Connects

Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Capped 1/2" (12.7 mm) MPX insert
2	Fill Line	3/4" (19.1 mm) ID X 1" (25.4 mm) OD C-Flex X 72" (183 cm)	1 1/2" (38.1 mm) Tri-clamp SterilEnz™
3	Vent Filter	1/4" (6.4 mm) ID X 1/2" (12.7 mm) OD C-Flex X 4" (10.2 cm)	Sterile Hydrophobic Vent Filter (0.2 micron PVDF - Pall Acro 50)
4	Recirculation/Sample line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 78" (198 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
5	Addition Line	3/8" (9.5 mm) ID X 5/8" (15.9 mm) OD C-Flex X 24" (61 cm)	Plugged 3/8" (9.5 mm) MPX body

Standard BPC Configurations (CX5-14 Film)

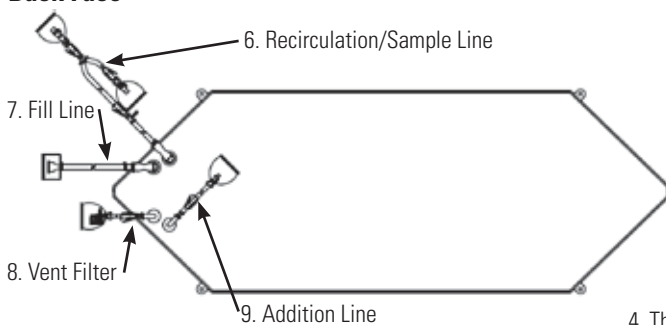
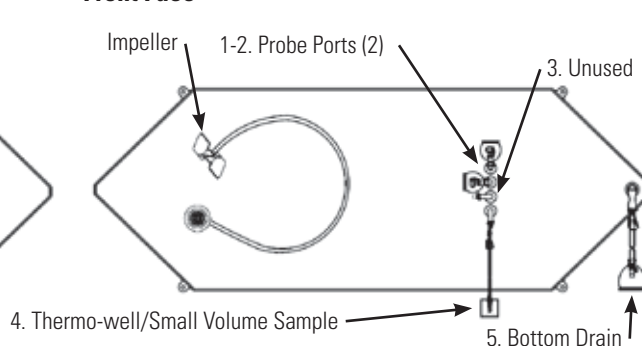
Powder-Liquid Applications with Probe Ports and Thermo-well—Part number SH30752.02
For use with tubing welder and with CPC® Quick Connects

Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Recirculation/Sample Line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 78" (198 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
2	Addition Line	1/2" (12.7 mm) ID X 5/8" (15.9 mm) OD C-Flex X 48" (122 cm)	Plugged 1/2" (12.7 mm) MPX body
3-4	Probe Ports (2)	None	Pall™ Kleenpak™ Aseptic Connector KPCHT Series (Female)
5	Unused	None	Plug
6	Thermo-well/ Small Volume Sample	Thermo-well Adapter for 1/8" (3.2 mm) Diameter 1/8" (3.2 mm) ID X 1/4" (6.4 mm) OD C-Flex X 12" (30 cm)	Luer and SmartSite® Valve Port
7	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Plugged 1/2" (12.7 mm) MPX body
8	Powder Addition Port	3" (76 mm) Sanitary Fitting, Tri-clamp	Cap with gasket

Standard BPC Configurations (CX5-14 Film)

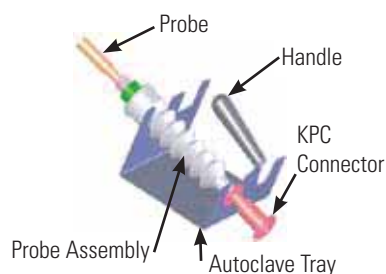
Liquid-Liquid Applications with Probe Ports and Thermo-well—Part number SH30755.02
For use with tubing welder and with CPC® Quick Connects

Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1-2	Probe Ports (2)	None	Pall Kleenpak Aseptic Connector KPCHT Series (Female)
3	Unused	None	Plug
4	Thermo-well/ Small Volume Sample	Thermo-well Adapter for 1/8" (3.2 mm) Diameter 1/8" (3.2 mm) ID X 1/4" (6.4 mm) OD C-Flex X 12" (30 cm)	Luer and SmartSite Valve Port
5	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Capped 1/2" (12.7 cm) MPX insert
6	Recirculation/Sample line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 78" (198 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
7	Fill Line	3/4" (19.1 mm) ID X 1" (25.4 mm) OD C-Flex X 72" (183 cm)	1 1/2" Tri-clamp SterilEnz
8	Vent Filter	1/4" (6.4 mm) ID X 1/2" (12.7 mm) OD C-Flex X 4" (10.2 cm)	Sterile Hydrophobic Vent Filter (0.2 micron PVDF - Pall Acro 50)
9	Addition Line	3/8" (9.5 mm) ID X 5/8" (15.9 mm) OD C-Flex X 24" (61 cm)	Plugged 3/8" (9.5 mm) MPX body

Ordering Information for Standard Products

Autoclave Tray and Probe Kits:

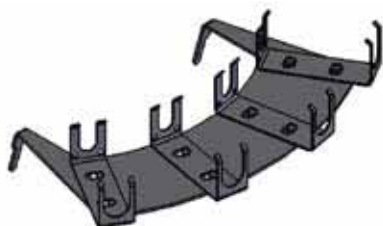


Additional Information on Autoclave Tray:

- Fabricated from stainless steel
- Plastic carry handle for easy transport right out of the autoclave
- Positions probes on 15% incline for greater probe/membrane longevity
- Will restrain probe bellows from collapsing during sterilization
- Probe holder accommodates two probes

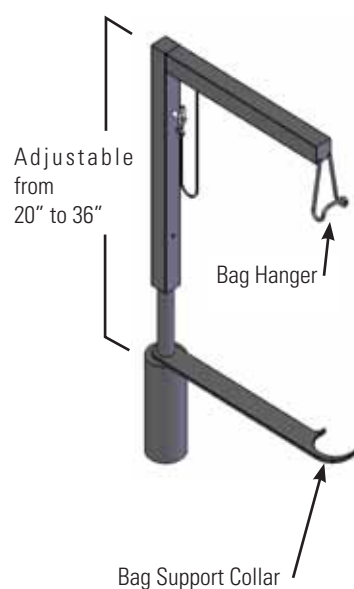
Probe Shelf:

The S.U.M. can be equipped with a probe shelf for probe support and retention.



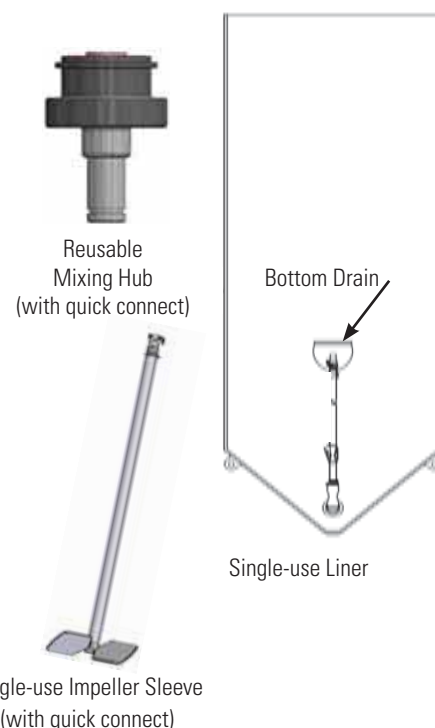
Powdertainer Hanger:

The Single-Use Mixer (S.U.M.) can be equipped with a Thermo Scientific HyClone Powdertainer hanger if so desired. When adding solids to liquids, this optional feature enables utilization of the Powdertainer powder feed system. The Powdertainer hanger can be used to support full 1, 5 or 25 Kg Powdertainers and positions the 3" sanitary connectors for bag to bag connection and solids transfer.



Open-Top Mixing (OTM) use:

The S.U.M. can be equipped with a reusable mixing hub accessory to enable use of open top liners and single-use impeller sleeves. The OTM option is a non-sterile easy-to-use mixing option. The reusable hub is simply placed into the motor's bearing port receiver and latched into place. The single-use impeller sleeve attaches to the hub's quick connect end. With an open liner in position and a drive shaft inserted the system is ready to use.



Accessories:

Part Number	Description	
SH30720.01	Probe Assembly (non-sterile)	Used to package probes (not supplied) for sterilization and to aseptically connect them to the S.U.M. BPC.
SV20664.01	Heavy Duty Tubing Clamp	Reusable tubing clamp used on probe ports when connecting probe assembly.
SV20664.02	Heavy Duty Tubing Clamp (4 pack of SV20664.01)	
SV20664.03	Heavy Duty Tubing Clamp (10 pack of SV20664.01)	
SV20750.01	S.U.M. thermo-well/sample port	Used for RTD calibration/validation.
SV20778.01	RTD	Pt100 Resistance Temperature Detector for use with S.U.M BPC thermo-well/sampling port.
SV50177.01	Autoclave Tray for Probe Kits (stainless steel)	Support tray which allows the probes to be safely autoclaved.
SH30845.01	Sterile Sampling Manifold with luer lock (individual)	Available for aseptic luer connection or welding onto the sample line to take sample sets.
SH30845.02	Sterile Sampling Manifold with luer lock (10 pack)	
SV50218	Load Cells*	Installed by manufacturer or end-user
SV50177.95	Probe Shelf	Support shelf for use with probe assemblies.
SV50187.01	Powdertainer Hanger with Support Collar	To support BPCs during Powdertainer attachment
SV50177.77	Reusable Mixing Hub	Required for use with single-use impeller sleeve
SH30762.03	Single-use Liner	Bottom drain liner with 72" (182.9 cm) of ½" (12.7 mm) C-Flex tubing and an MPX insert connector, CX3-9 Film
SH30749.10	Single-use Impeller Sleeve	For Open-Top Mixing

* For more information on Load Cell options refer to Data Sheet 048.

Hardware Standard Products

Non-Heated:

Part Number	Description	
SV50215.01	1000 L S.U.M., 120 VAC, Single Phase	Includes: 304 stainless steel outer support container with swivel caster platform, variable speed agitation controller, motor, drive assembly with shaft and standard tool set
SV50215.02	1000 L S.U.M., 240 VAC, Single Phase	

Water Jacket:

Part Number	Description	
SV50215.03	1000 L S.U.M., 120 VAC, Single Phase	Includes: 304 stainless steel outer support container with swivel caster platform, variable speed agitation controller, motor, drive assembly with shaft, integrated water jacket and standard tool set
SV50215.04	1000 L S.U.M., 240 VAC, Single Phase	

Custom BPC Options:

Tubing Type	C-Flex (clear, white, and ADCF), Silicone, PVC, PharMed® or PharmaPure®
Tubing Size	Specific Lengths of 1/8 to 1" (3.18 to 25.4 mm) ID — depending on type of tubing chosen
Connectors	Luer — 1/8 to 1/2" (3.18 to 12.7 mm) ID CPC — 1/4 to 3/4" (6.35 to 19 mm) ID SIP Connector — 1/4 to 3/4" (6.35 to 19 mm) ID Tri-clamp — 1/8" to 1" (3.18 to 25.4mm) ID Mini-Tri-clamp — 1/8 to 1/2" (6.35 to 12.7 mm) ID Aseptic Connection Device — All available sizes of Pall Kleenpak and BioQuate™ DAC
Others	Needle-free sample port (SmartSite or Clave®) Filter Capsule (Millipore®, Pall, Sartorius™, Domnick Hunter®, Meissner®, Other)

Please Note: Not all options are available for all ports. Customization of port type and location, chamber dimensions or mixing assembly is not available. For additional information, please refer to the Selection Guides in the 2008 BPC Catalog.

Presentation (as dry BPC systems):

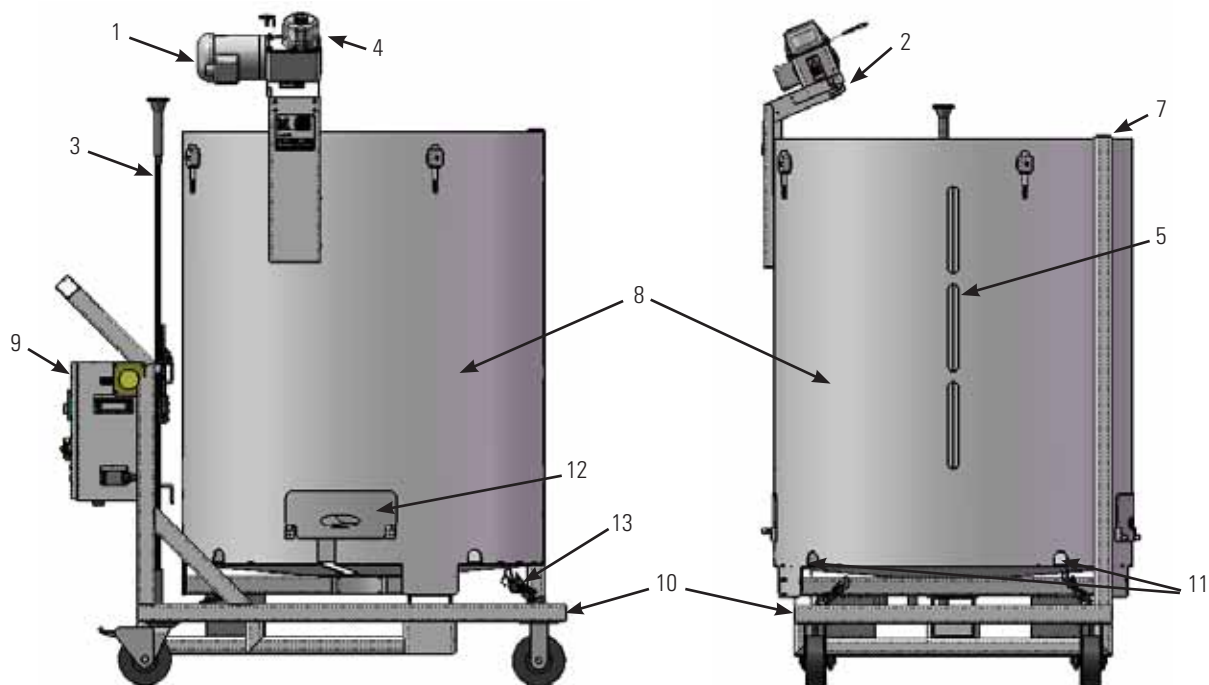
Outer Packaging	Supplied 'flat-packed' Two polyethylene outer layers
Label	Description Product code Lot number Expiry date on outer packaging and shipping container
Sterilization	Irradiation (25 to 38 kGy) inside outer packaging
Shipping Container	Durable cardboard carton
Documentation	Certificate of Analysis provided with each lot for each delivery

Hardware Features

1000 L S.U.M.:

The stainless steel outer support container contains the following features:

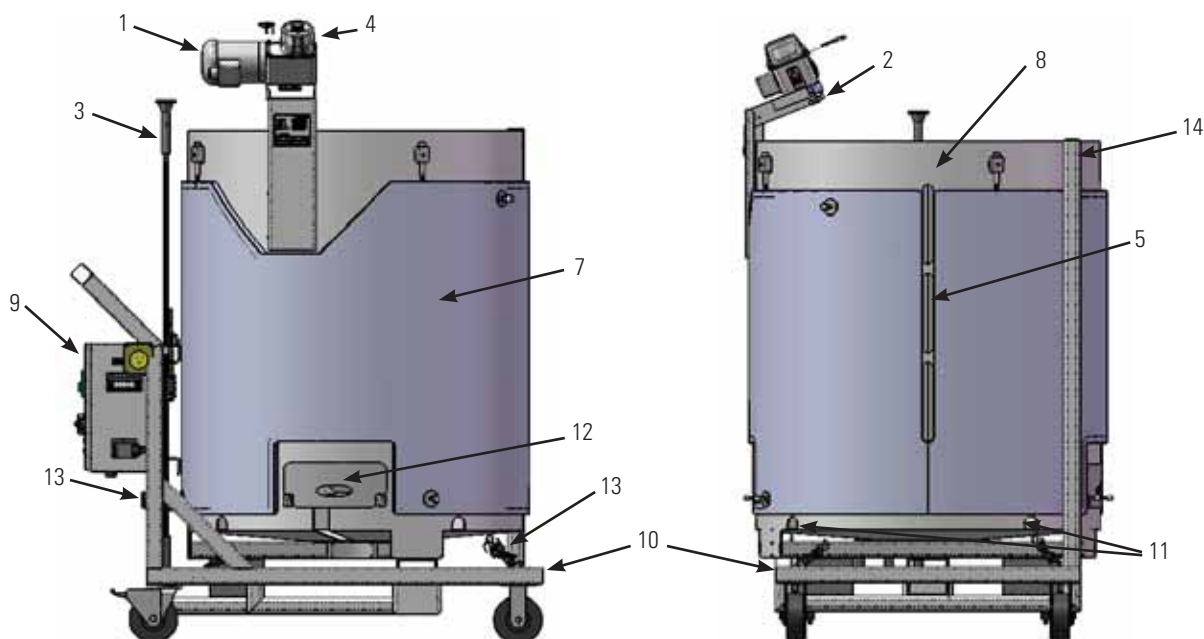
- | | | |
|-------------------------------------|--|---------------------------------------|
| 1. Mixer motor | 6. Standard tool set (not shown) | 11. Bottom cut outs for BPC alignment |
| 2. Bearing port receiver with clamp | 7. Powdertainer Hanger Mount | 12. Probe Access Door |
| 3. Drive shaft | 8. Stainless steel (304) outer support container | 13. Stretch Hooks |
| 4. Mixing assembly with shield | 9. Control panel | |
| 5. Liquid sight window | 10. Platform with large diameter wheels | |



1000 L with Water Jacket:

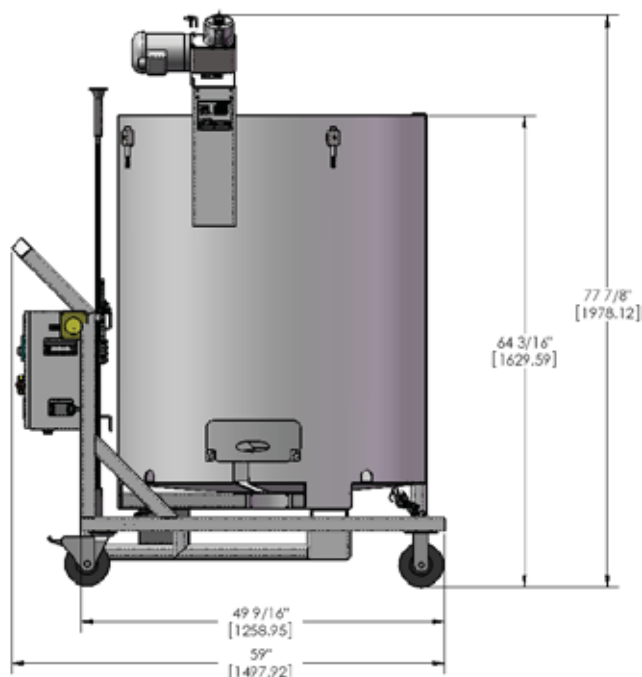
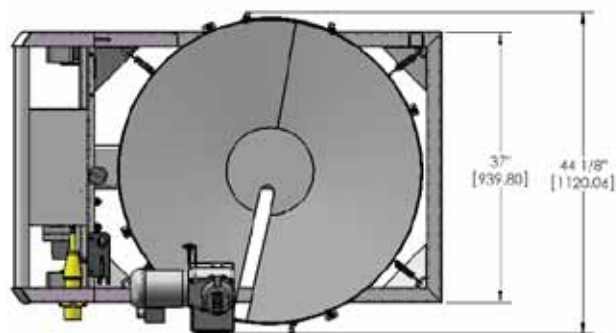
The stainless steel outer support container contains the following features:

- | | | |
|-------------------------------------|--|---------------------------------------|
| 1. Mixer motor | 6. Standard tool set (not shown) | 11. Bottom cut outs for BPC alignment |
| 2. Bearing port receiver with clamp | 7. Water Jacket | 12. Probe access door |
| 3. Drive shaft | 8. Stainless steel (304) outer support container | 13. Jacket quick connect coupling |
| 4. Mixing assembly with shield | 9. Control panel | 14. Powdertainer Hanger Mount |
| 5. Liquid sight window | 10. Platform with large diameter wheels | 15. Stretch Hooks |

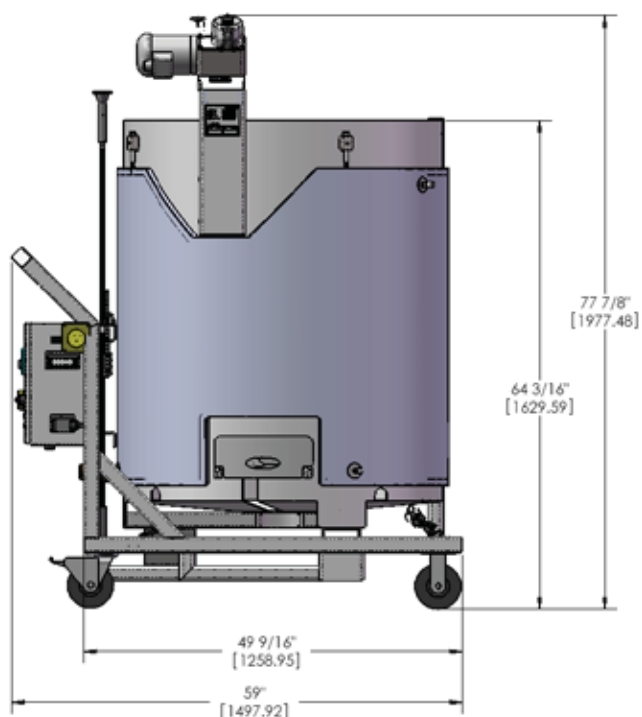
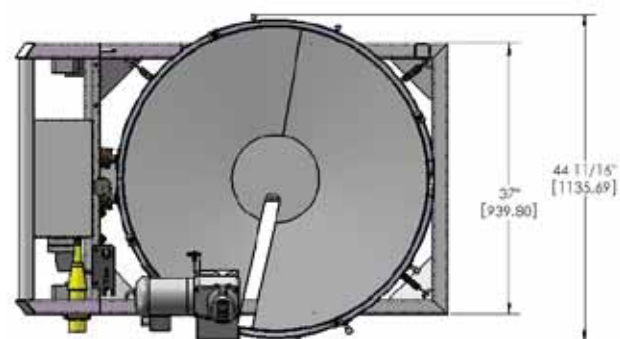


Outer Support Container (units in inches [mm])

1000 L S.U.M.:



1000 L Jacketed S.U.M.:



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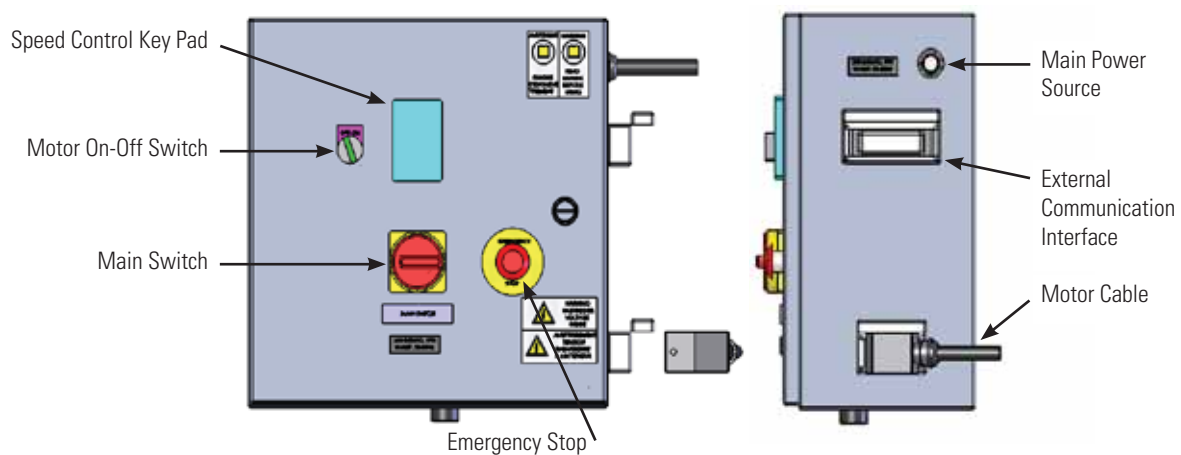
3.4.2 1000 L Hardware Specifications Non-Heated

Vessel Geometry	Rated Liquid Working Volume	1000 L
	Minimum Liquid Working Volume	200 L
	BPC Chamber Diameter	41.52" (105.4 cm)
	BPC Chamber Shoulder Height	61.9" (157.2 cm)
	Liquid Height @ Rated Working Volume	45.5" (115.6 cm)
	Fluid Geometry @ Working Volume (height/diameter) Ratio	1.1:1
	Overall Geometry (height/diameter) Ratio	1.2:1
	Hold up volume (typical)	<300 mL
Impeller	Impeller (quantity X blade count)	1 x 3
	Impeller Blade Pitch (angle)	45°
	Impeller Diameter	7.875" (20 cm)
Mixing	Maximum Mixing Rate (revolutions per minute)	350 rpm
	Overall Drive Shaft Length	60" (152.4 cm)
Drive Motor	Programmable VFD, Remote Panel Interface	standard
	Mixer Motor Drive (voltage, phase, amp)	208 VAC, three, 15 Amp
	Motor Power Rating	0.5 hp (372.8 W)
	Motor Torque Rating	80 lb _f -in (9.04 Nm)
	Gear Reduction	5:1
Support Container	Primary Construction Material (Outer Support Container)	304 Stainless Steel
	Primary Construction Material (Inner Support Tank)	304 Stainless Steel
	Skid Width	44.5" (113 cm)
	Skid Depth	59" (150 cm)
	Skid Height	78" (198 cm)
	Dry Skid Weight (mass)	711 lb (323 kg)
	Wet Skid Weight - Rated Working Volume (mass)	3087 lbs (1400 kg)
General	Minimum Ceiling Height Recommendations	11' (335 cm)
	Electrical Power Supply Requirement (voltage, phase, amp)	120 or 240 VAC, single, 15 Amp Non GFCI circuit
	Electrical Class Ratings	ETL, CE, IP-56
	Contact Materials Biocompatibility	USP Class VI
	Validated System Reliability (minimum)	0.9 @ 90%
	Weigh Scale Platform Area (minimum area for caster stands)	48" x 48" (122 cm x 122 cm)

3.4.3 1000 L Hardware Specifications Water Jacket

Vessel Geometry	Rated Liquid Working Volume	1000 L
	Minimum Liquid Working Volume	200 L
	BPC Chamber Diameter	41.52" (105.4 cm)
	BPC Chamber Shoulder Height	61.9" (157.2 cm)
	Liquid Height @ Rated Working Volume	45.5" (115.6 cm)
	Fluid Geometry @ Working Volume (height/diameter) Ratio	1.1:1
	Overall Geometry (height/diameter) Ratio	1.2:1
	Hold up volume (typical)	<300 mL
Impeller	Impeller (quantity X blade count)	1 x 3
	Impeller Blade Pitch (angle)	45°
	Impeller Diameter	7.875" (20 cm)
Mixing	Maximum Mixing Rate (revolutions per minute)	350 rpm
	Overall Drive Shaft Length	60" (152.4 cm)
Drive Motor	Programmable VFD, Remote Panel Interface	standard
	Mixer Motor Drive (voltage, phase, amp)	208 VAC, three, 15 Amp
	Motor Power Rating	0.5 hp (372.8 W)
	Motor Torque Rating	80 lb _f -in (9.04 Nm)
	Gear Reduction	5:1
Support Container	Primary Construction Material (Outer Support Container)	304 Stainless Steel
	Primary Construction Material (Inner Support Tank)	304 Stainless Steel
	Skid Width	44.5" (113 cm)
	Skid Depth	59" (150 cm)
	Skid Height	78" (198 cm)
	Dry Skid Weight (mass)	711 lb (323 kg)
	Wet Skid Weight - Rated Working Volume (mass)	3087 lbs (1400 kg)
General	Minimum Ceiling Height Recommendations	11' (335 cm)
	Electrical Power Supply Requirement (voltage, phase, amp)	120 or 240 VAC, single, 15 Amp Non GFCI circuit
	Electrical Class Ratings	ETL, CE, IP-56
	Contact Materials Biocompatibility	USP Class VI
	Validated System Reliability (minimum)	0.9 @ 90%
	Weigh Scale Platform Area (minimum area for caster stands)	48" x 48" (122 cm x 122 cm)

3.4.4 1000 L Control Panel Layout



3.5 2000 L Single-Use Mixer

- 3.5.1 2000 L S.U.M. Data Sheet
- 3.5.2 2000 L S.U.M. Hardware Specifications - Non-Heated
- 3.5.3 2000 L S.U.M. Hardware Specifications - Water Jacket
- 3.5.4 2000 L Control Panel Layout

The Thermo Scientific HyClone Single-Use Mixer (S.U.M.) is part of a product family which provides efficient and powerful mixing for a wide range of applications based on a conventional stirred tank design. For use with powder hydration for preparation of critical sterile and non-sterile solutions and suspensions.

The current range includes units with maximum volumes of 50, 200, 500, 1000 and 2000 L.

Thermo Scientific HyClone Single-Use Mixer (S.U.M.) 2000 L

Overview:

The Single-Use Mixer is based on the same concept as the Thermo Scientific HyClone Single-Use Bioreactor (S.U.B.) with a single-use BioProcess Container (BPC®), an integrated impeller and a reusable hardware system providing support, mixing motor and control system. As opposed to smaller S.U.M. systems, the 2000 L S.U.M. is intended as a fixed rather than a mobile unit.

The range of product solutions included in this data sheet expand the functionality offered by the S.U.M. products.

The offerings include:

Stainless Steel Hardware Systems

- With or without heating/cooling jacket
- Cutout sections to facilitate S.U.M. BPC loading and monitoring probe capability
- Location mechanism for S.U.M. BPC

S.U.M. BPC Options:

- Open top liner media/buffer preparation
- Closed BPC with powder port for contained media/buffer preparation

- Closed BPC with powder port and monitoring probe capability
- Closed BPC for liquid-liquid mixing of critical sterile solutions such as pooling of fractions or processing intermediate solutions
- Closed BPC for liquid-liquid mixing with monitoring probe capability



2000 L S.U.M.

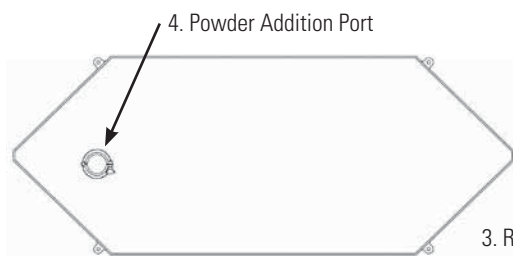
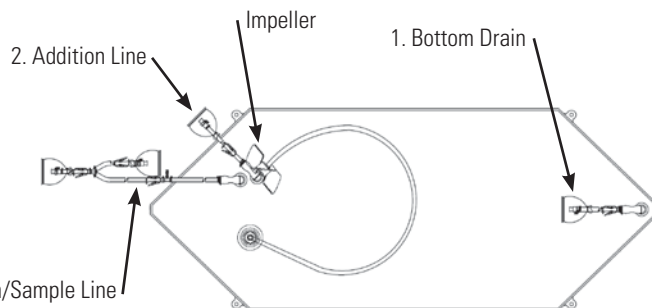
Item	2000 L Non-Heated	2000 L Water Jacket Heater
Rated Liquid Working Volume	2000 L	
Minimum Liquid Working Volume	400 L	
BPC Chamber Diameter	53" (135 cm)	
BPC Chamber Shoulder Height	73" (185 cm)	
Liquid Height @ Rated Working Volume	55" (140 cm)	
Overall Geometry (height/diameter ratio)	1.1:1	
Fluid Geometry @ Working Volume (height/diameter) Ratio	1:1	
Impeller (quantity x blade count)	1 x 3	
Impeller Diameter	9.85" (25 cm)	
Hold-Up Volume (typical)	<1 L	
Electrical Power Supply Requirement (voltage, phase, amp)	120 VAC, single, 15 Amp—Non GFCI circuit and 240 VAC, single, 15 Amp—Non GFCI circuit	
Skid Width	55" (140 cm)	
Skid Depth	55" (188 cm)	
Skid Height	74" (188 cm)	
Dry Skid Weight (mass)	1500 lbs (680 kg)	1750 lbs (794 kg)
Wet Skid Weight—Rated Working Volume (mass)	5909 lbs (2680 kg)	6159 lbs (2794 kg)
Minimum Ceiling Height Requirement	11' (335cm)	
S.U.M. Recommended Operating Parameters		
Temperature	2-40°C	
Motor Speed	0-350 rpm	
Volume Range	20-100% of Nominal	
Maximum CTM Pressure	.2 psig	
Continuous Operating Time	21 days*	

*Mixing time at nominal volume only.

Standard BPC Configurations (CX5-14 Film)

Powder-Liquid Applications—Part number SH30770.01

For use with tubing welder and with CPC® Quick Connects

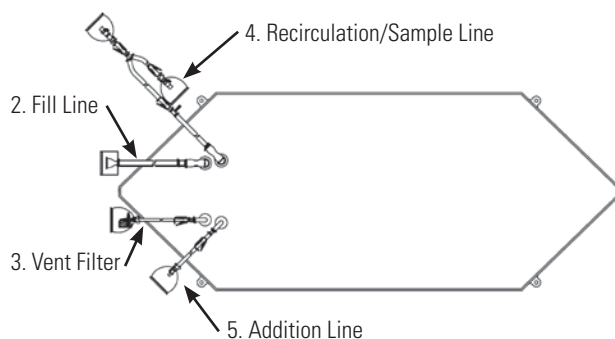
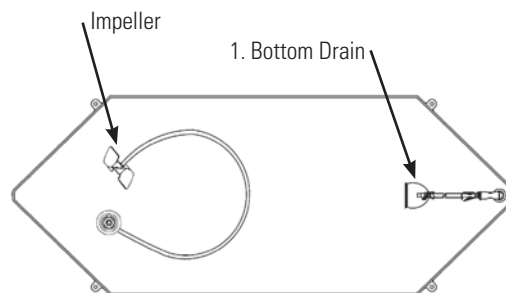
Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex® X 48" (122 cm)	Capped 1/2" (12.7 mm) MPX insert
2	Addition Line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 72" (183 cm)	Plugged 1/2" (12.7 mm) MPX body
3	Recirculation/ Sample line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 78" (198 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
4	Powder Addition Port	3" (76 mm) Sanitary Fitting, Tri-clamp	Cap with gasket

Standard BPC Configurations (CX5-14 Film)

Liquid-Liquid Applications—Part number SH30769.01

For use with tubing welder and with CPC® Quick Connects

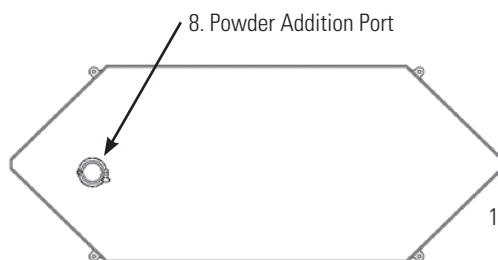
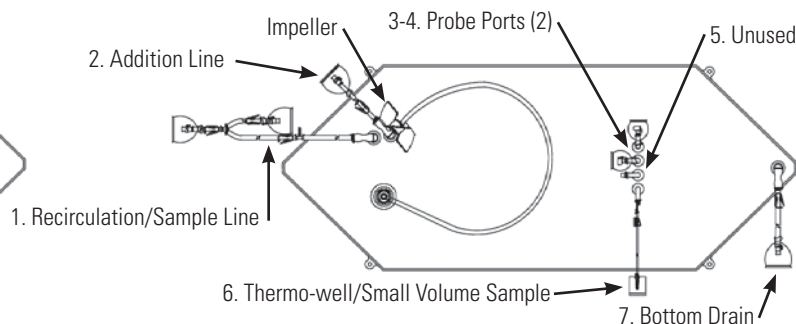
Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Capped 1/2" (12.7 mm) MPX insert
2	Fill Line	3/4" (19.1 mm) ID X 1" (25.4 mm) OD C-Flex X 72" (183 cm)	1 1/2" (38.1 mm) Tri-clamp SterilEnz™
3	Vent Filter	1/4" (6.4 mm) ID X 1/2" (12.7 mm) OD C-Flex X 4" (10.2 cm)	Sterile Hydrophobic Vent Filter (0.2 micron PVDF - Pall Acro 50)
4	Recirculation/ Sample line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 78" (198 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
5	Addition Line	3/8" (9.5 mm) ID X 5/8" (15.9 mm) OD C-Flex X 24" (61 cm)	Plugged 3/8" (9.5 mm) MPX body

Standard BPC Configurations (CX5-14 Film)

Powder-Liquid Applications with Probe Ports and Thermo-well—Part number SH30770.02

For use with tubing welder and with CPC® Quick Connects

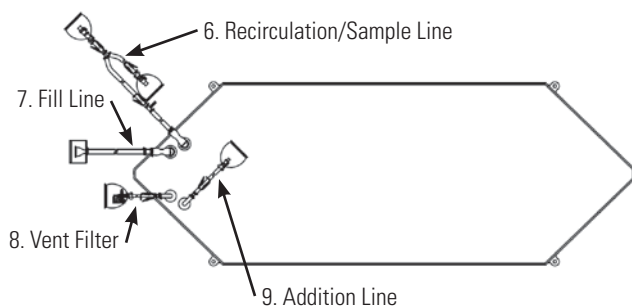
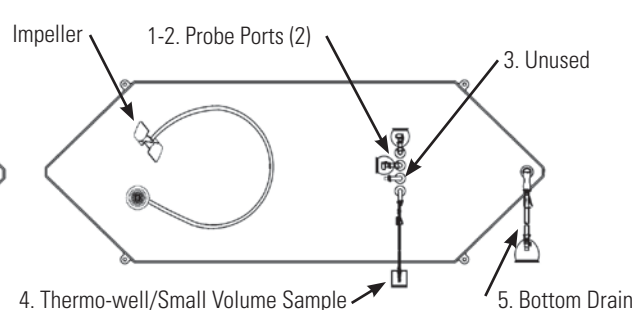
Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Recirculation/ Sample Line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 78" (198 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
2	Addition Line	1/2" (12.7 mm) ID X 5/8" (15.9 mm) OD C-Flex X 48" (122 cm)	Plugged 1/2" (12.7 mm) MPX body
3-4	Probe Ports (2)	None	Pall™ Kleenpak™ Aseptic Connector KPCHT Series (Female)
5	Unused	None	Plug
6	Thermo-well/ Small Volume Sample	Thermo-well Adapter for 1/8" (3.2 mm) Diameter 1/8" (3.2 mm) ID X 1/4" (6.4 mm) OD C-Flex X 12" (30 cm)	Luer and SmartSite® Valve Port
7	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Plugged 1/2" (12.7 mm) MPX body
8	Powder Addition Port	3" (76 mm) Sanitary Fitting, Tri-clamp	Cap with gasket

Standard BPC Configurations (CX5-14 Film)

Liquid-Liquid Applications with Probe Ports and Thermo-well—Part number SH30769.02

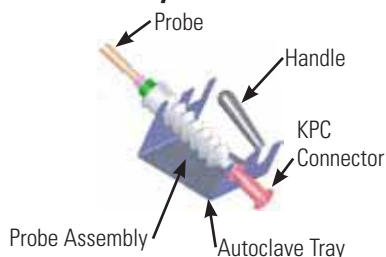
For use with tubing welder and with CPC® Quick Connects

Back Face**Front Face**

Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1-2	Probe Ports (2)	None	Pall Kleenpak Aseptic Connector KPCHT Series (Female)
3	Unused	None	Plug
4	Thermo-well/ Small Volume Sample	Thermo-well Adapter for 1/8" (3.2 mm) Diameter 1/8" (3.2 mm) ID X 1/4" (6.4 mm) OD C-Flex X 12" (30 cm)	Luer and SmartSite Valve Port
5	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Capped 1/2" (1.27 cm) MPX insert
6	Recirculation/ Sample line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 78" (198 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
7	Fill Line	3/4" (19.1 mm) ID X 1" (25.4 mm) OD C-Flex X 72" (183 cm)	1 1/2" Tri-clamp SterilEnz
8	Vent Filter	1/4" (6.4 mm) ID X 1/2" (12.7 mm) OD C-Flex X 4" (10.2 cm)	Sterile Hydrophobic Vent Filter (0.2 micron PVDF - Pall Acro 50)
9	Addition Line	3/8" (9.5 mm) ID X 5/8" (15.9 mm) OD C-Flex X 24" (61 cm)	Plugged 3/8" (9.5 mm) MPX body

Ordering Information for Standard Products

Autoclave Tray and Probe Kits:



Additional Information on Autoclave Tray:

- Fabricated from stainless steel
- Plastic carry handle for easy transport right out of the autoclave
- Positions probes on 15% incline for greater probe/membrane longevity
- Will restrain probe bellows from collapsing during sterilization
- Probe holder accommodates two probes

Probe Shelf:

The S.U.M. can be equipped with a probe shelf for probe support and retention.



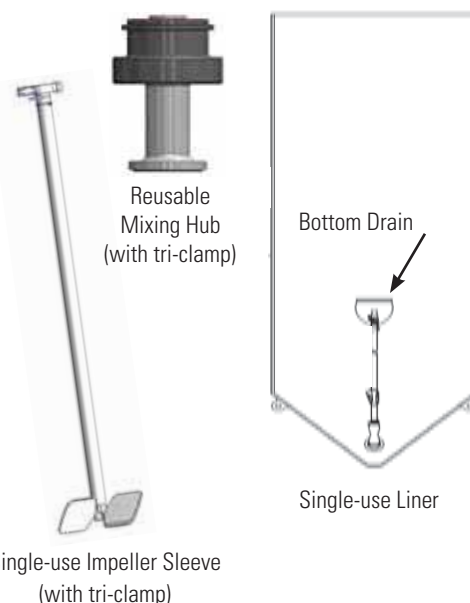
Powdertainer Hanger:

The Single-Use Mixer (S.U.M.) can be equipped with a Thermo Scientific HyClone Powdertainer hanger if so desired. When adding solids to liquids, this optional feature enables utilization of the Powdertainer powder feed system. The Powdertainer hanger can be used to support full 1, 5 or 25 Kg Powdertainers and positions the 3" sanitary connectors for bag to bag connection and solids transfer.



Open-Top Mixing (OTM) use:

The S.U.M. can be equipped with a reusable mixing hub accessory to enable use of open top liners and single-use impeller sleeves. The OTM option is a non-sterile easy-to-use mixing option. The reusable hub is simply placed into the motor's bearing port receiver and latched into place. The single-use impeller sleeve attaches to the hub's tri-clamp end. With an open liner in position and a drive shaft inserted the system is ready to use.



Accessories:

Part Number	Description	
SH30720.01	Probe Assembly (non-sterile)	Used to package probes (not supplied) for sterilization and to aseptically connect them to the S.U.M. BPC.
SV20664.01	Heavy Duty Tubing Clamp	Reusable tubing clamp used on probe ports when connecting probe assembly.
SV20664.02	Heavy Duty Tubing Clamp (4 pack of SV20664.01)	
SV20664.03	Heavy Duty Tubing Clamp (10 pack of SV20664.01)	
SV20750.01	S.U.M. thermo-well/sample port	Used for RTD calibration/validation.
SV20778.01	RTD	Pt100 Resistance Temperature Detector for use with S.U.M BPC thermo-well/sampling port.
SV50177.01	Autoclave Tray for Probe Kits (stainless steel)	Support tray which allows the probes to be safely autoclaved.
SH30845.01	Sterile Sampling Manifold with luer lock (individual)	Available for aseptic luer connection or welding onto the sample line to take sample sets.
SH30845.02	Sterile Sampling Manifold with luer lock (10 pack)	
SV50227	Load Cells*	Installed by manufacturer or end-user
SV50177.96	Probe Shelf	Support shelf for use with probe assemblies.
SV50187.03	Powdertainer Hanger with Support Collar	To support BPCs during Powdertainer attachment
SV50177.78	Reusable Mixing Hub	Required for use with single-use impeller sleeve
SH30762.05	Single-use Liner	Bottom drain liner with 72" (182.9 cm) of ½" (12.7 mm) C-Flex tubing and an MPX insert connector, CX3-9 Film
SH30772.01	Single-use Impeller Sleeve	For Open-Top Mixing

* For more information on Load Cell options refer to Data Sheet 048.

Hardware Standard Products**Non-Heated:**

Part Number	Description	
SV50216.01	2000 L S.U.M., 120 VAC, Single Phase	Includes: 304 stainless steel outer support container with swivel caster platform, variable speed agitation controller, motor, drive assembly with shaft and standard tool set
SV50216.02	2000 L S.U.M., 240 VAC, Single Phase	

Water Jacket:

Part Number	Description	
SV50216.03	2000 L S.U.M., 120 VAC, Single Phase	Includes: 304 stainless steel outer support container with swivel caster platform, variable speed agitation controller, motor, drive assembly with shaft, integrated water jacket and standard tool set
SV50215.04	2000 L S.U.M., 240 VAC, Single Phase	

Custom BPC Options:

Tubing Type	C-Flex (clear, white, and ADCF), Silicone, PVC, PharMed® or PharmaPure®
Tubing Size	Specific Lengths of 1/8 to 1" (3.18 to 25.4 mm) ID — depending on type of tubing chosen
Connectors	Luer — 1/8 to 1/2" (3.18 to 12.7 mm) ID CPC — 1/4 to 3/4" (6.35 to 19 mm) ID SIP Connector — 1/4 to 3/4" (6.35 to 19 mm) ID Tri-clamp — 1/8" to 1" (3.18 to 25.4mm) ID Mini-Tri-clamp — 1/8 to 1/2" (6.35 to 12.7 mm) ID Aseptic Connection Device — All available sizes of Pall Kleenpak and BioQuate™ DAC
Others	Needle-free sample port (SmartSite or Clave®) Filter Capsule (Millipore®, Pall, Sartorius™, Domnick Hunter®, Meissner®, Other)

Please Note: Not all options are available for all ports. Customization of port type and location, chamber dimensions or mixing assembly is not available. For additional information, please refer to the Selection Guides in the 2008 BPC Catalog.

Presentation (as dry BPC systems):

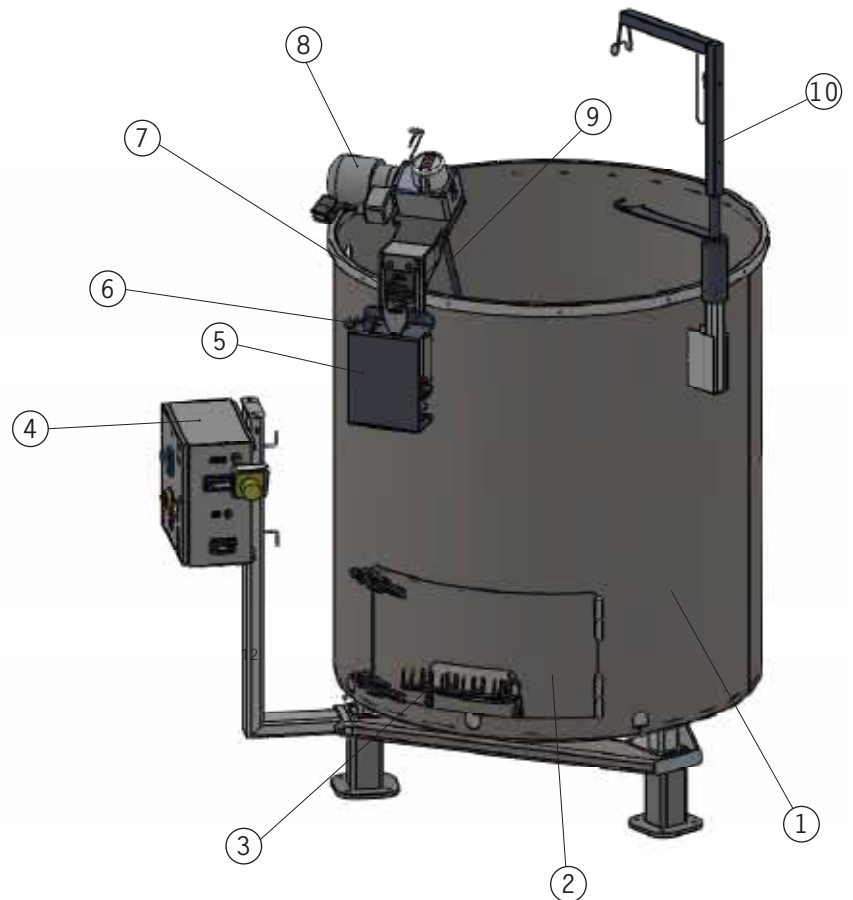
Outer Packaging	Supplied 'flat-packed' Two polyethylene outer layers
Label	Description Product code Lot number Expiry date on outer packaging and shipping container
Sterilization	Irradiation (25 to 38 kGy) inside outer packaging
Shipping Container	Durable cardboard carton
Documentation	Certificate of Analysis provided with each lot for each delivery

Hardware Features

2000 L S.U.M.:

The stainless steel outer support container contains the following features:

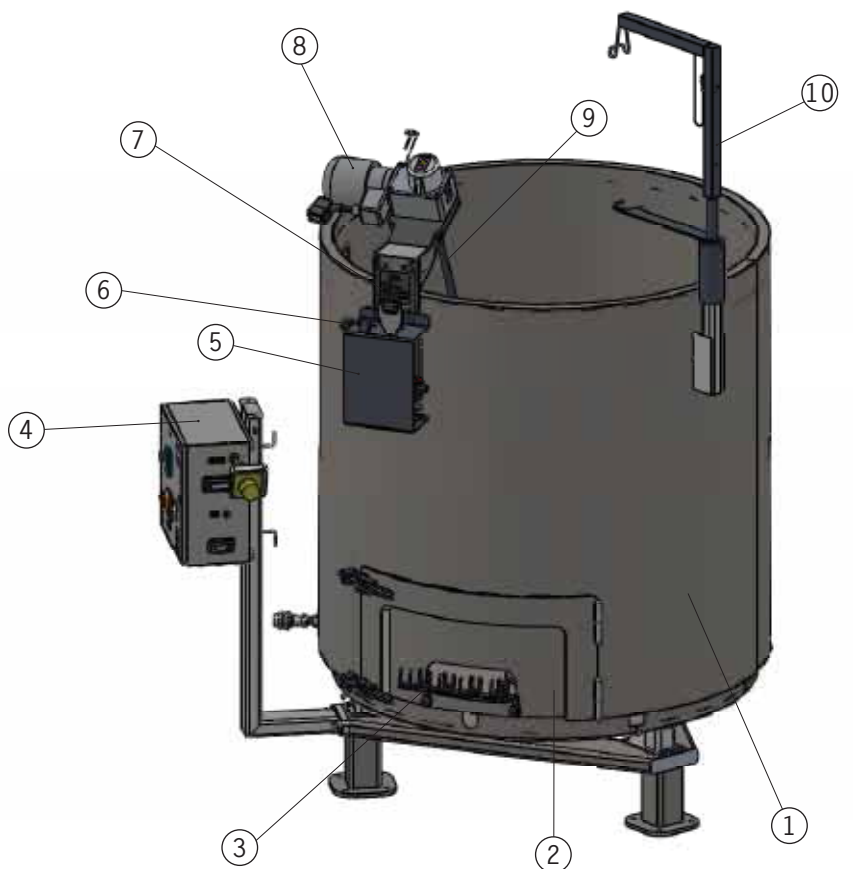
1. Non-jacketed vessel
2. Tank front access hatch
3. Probe window with probe shelf and clips attached
4. Electric panel
5. Tool mount bracket
6. Spanner, torque, combination wrenches
7. ID plate
8. Drive motor assembly
9. Drive shaft assembly
10. Powder arm assembly



2000 L with Water Jacket:

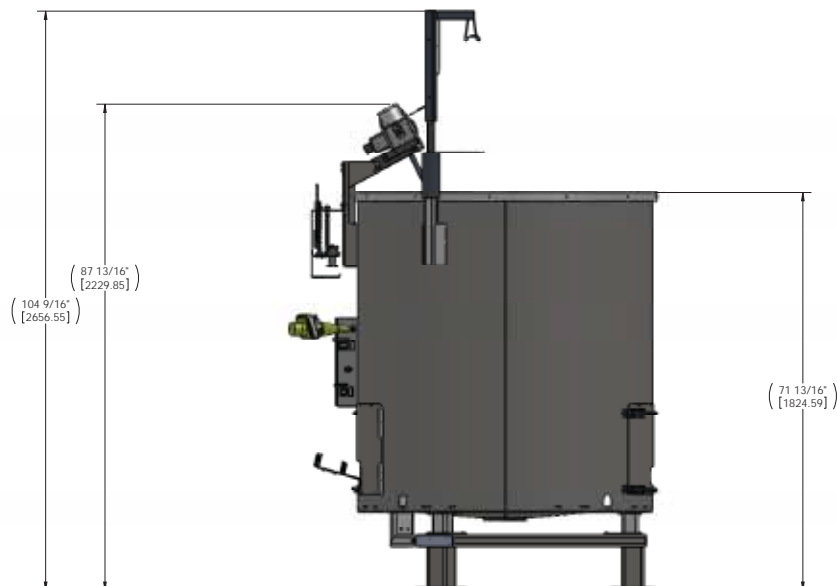
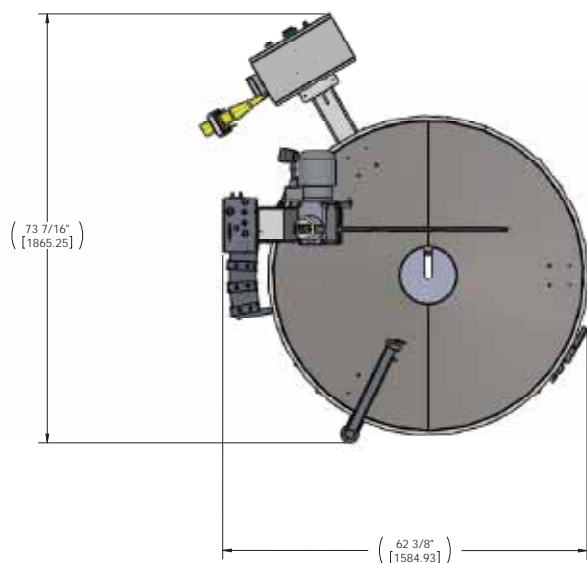
The stainless steel outer support container contains the following features:

1. Jacketed vessel
2. Tank front access hatch
3. Probe window with probe shelf and clips attached
4. Electric panel
5. Tool mount bracket
6. Spanner, torque, combination wrenches
7. ID plate
8. Drive motor assembly
9. Drive shaft assembly
10. Powder arm assembly

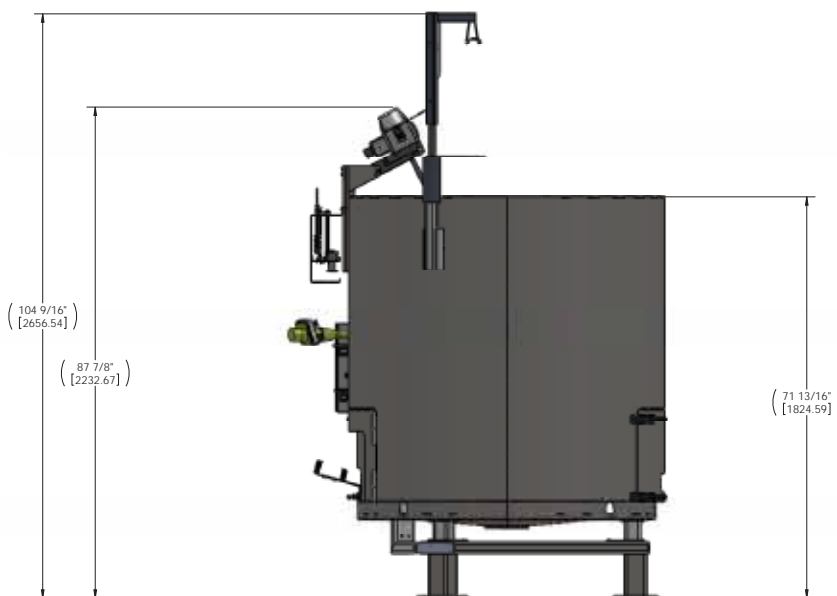
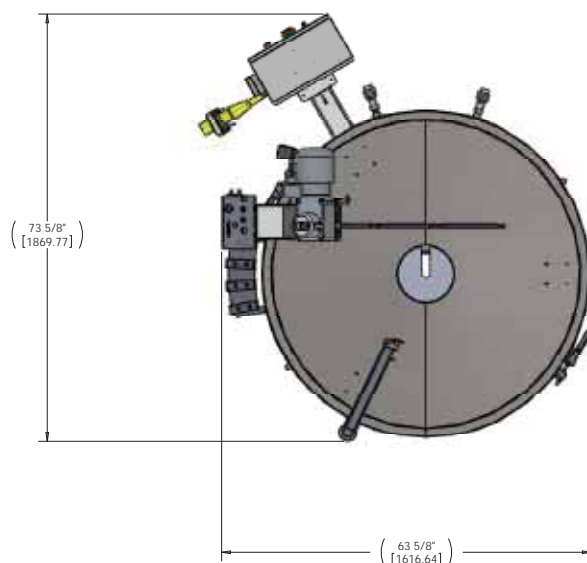


Outer Support Container (units in inches [mm])

2000 L S.U.M.:



2000 L Jacketed S.U.M.:



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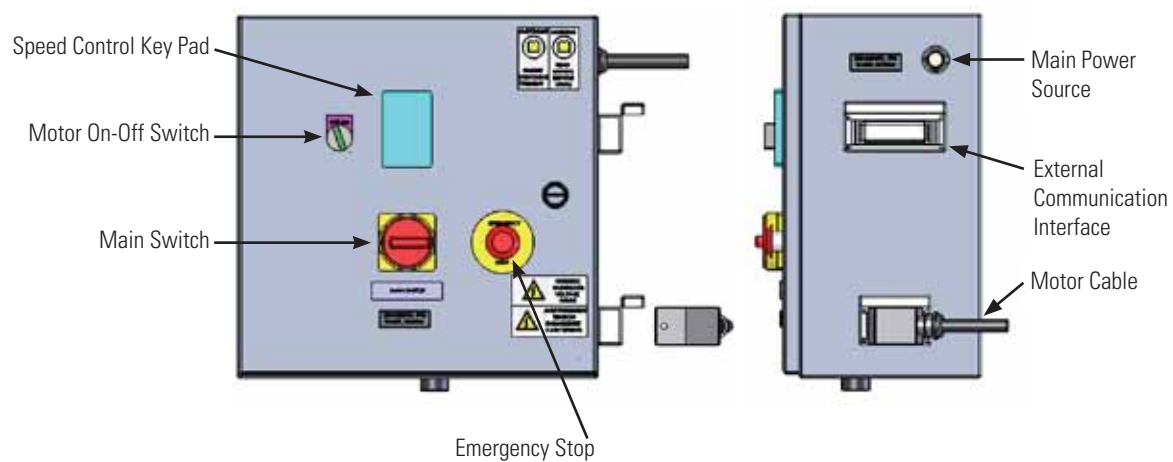
3.5.2 2000 L Hardware Specifications Non-Heated

Vessel Geometry	Rated Liquid Working Volume	2000 L
	Minimum Liquid Working Volume	400 L
	BPC Chamber Diameter	53" (135 cm)
	BPC Chamber Shoulder Height	73" (185 cm)
	Liquid Height @ Rated Working Volume	55" (140 cm)
	Fluid Geometry @ Working Volume (height/diameter) Ratio	1:1
	Overall Geometry (height/diameter) Ratio	1.1:1
	Hold up volume (typical)	<1 L
Impeller	Impeller (quantity X blade count)	1 x 3
	Impeller Blade Pitch (angle)	45°
	Impeller Diameter	9.85" (25 cm)
Mixing	Maximum Mixing Rate (revolutions per minute)	350 rpm
	Overall Drive Shaft Length	75" (190.5 cm)
Drive Motor	Programmable VFD, Remote Panel Interface	standard
	Mixer Motor Drive (voltage, phase, amp)	208 VAC, three, 15 Amp
	Motor Power Rating	1 hp (745.7 W)
	Motor Torque Rating	159 lb _f -in (18 Nm)
	Gear Reduction	5:1
Support Container	Primary Construction Material (Outer Support Container)	304 Stainless Steel
	Primary Construction Material (Inner Support Tank)	304 Stainless Steel
	Skid Width	55" (140 cm)
	Skid Depth	55" (140 cm)
	Skid Height	74" (188 cm)
	Dry Skid Weight (mass)	1500 lb (680 kg)
	Wet Skid Weight - Rated Working Volume (mass)	5909 lbs (2680 kg)
General	Minimum Ceiling Height Recommendations	11' (335 cm)
	Electrical Power Supply Requirement (voltage, phase, amp)	120 or 240 VAC, single, 15 Amp Non GFCI circuit
	Electrical Class Ratings	ETL, CE, IP-56
	Contact Materials Biocompatibility	USP Class VI
	Validated System Reliability (minimum)	0.9 @ 90%

3.5.3 2000 L Hardware Specifications Water Jacket

Vessel Geometry	Rated Liquid Working Volume	2000 L
	Minimum Liquid Working Volume	400 L
	BPC Chamber Diameter	53" (135 cm)
	BPC Chamber Shoulder Height	73" (185 cm)
	Liquid Height @ Rated Working Volume	55" (140 cm)
	Fluid Geometry @ Working Volume (height/diameter) Ratio	1:1
	Overall Geometry (height/diameter) Ratio	1.1:1
	Hold up volume (typical)	<1 L
Impeller	Impeller (quantity X blade count)	1 x 3
	Impeller Blade Pitch (angle)	45°
	Impeller Diameter	9.85" (25 cm)
Mixing	Maximum Mixing Rate (revolutions per minute)	350 rpm
	Overall Drive Shaft Length	75" (190.5 cm)
Drive Motor	Programmable VFD, Remote Panel Interface	standard
	Mixer Motor Drive (voltage, phase, amp)	208 VAC, three, 15 Amp
	Motor Power Rating	1 hp (745.7 W)
	Motor Torque Rating	159 lb _f -in (18 Nm)
	Gear Reduction	5:1
Support Container	Primary Construction Material (Outer Support Container)	304 Stainless Steel
	Primary Construction Material (Inner Support Tank)	304 Stainless Steel
	Skid Width	55" (140 cm)
	Skid Depth	55" (140 cm)
	Skid Height	74" (188 cm)
	Dry Skid Weight (mass)	1750 lb (794 kg)
	Wet Skid Weight - Rated Working Volume (mass)	6159 lbs (2794 kg)
General	Minimum Ceiling Height Recommendations	11' (335 cm)
	Electrical Power Supply Requirement (voltage, phase, amp)	120 or 240 VAC, single, 15 Amp Non GFCI circuit
	Electrical Class Ratings	ETL, CE, IP-56
	Contact Materials Biocompatibility	USP Class VI
	Validated System Reliability (minimum)	0.9 @ 90%

3.5.4 2000 L Control Panel Layout



3.6 Docking Station Single-Use Mixer

- 3.6.1 Docking S.U.M. Data Sheet
- 3.6.2 Docking S.U.M. Hardware Specifications
- 3.6.3 Docking Control Panel Layout

Thermo Scientific HyClone Single-Use Mixer (S.U.M.) Docking Station System

The Thermo Scientific HyClone Single-Use Mixer (S.U.M.) is a product family of systems providing powerful and efficient mixing based on a conventional stirred tank design. It is available in a wide range of options to cover mixing applications from powder hydration to preparation of critical sterile solutions and suspensions.

The S.U.M. Docking Station system is optimized for high throughput applications for volumes up to 1000 L.

Overview:

The S.U.M. is based on the same concept as the Thermo Scientific HyClone Single-Use Bioreactor (S.U.B.) with a single-use BioProcess Container (BPC) with an integrated impeller and a hardware system providing support, mobility, mixing motor and controller. In contrast to the other options in the S.U.M. product family the docking station system has the mixing motor mounted on a separate docking station rather than on the tank itself. This allows the mixing motor to link with a range of separate tanks. Easy-to-use motor height and angle adjustment combined with a secure mechanism to locate and lock the docking station and tank in place make changeover of tanks simple and rapid.

The stainless steel tank options include:

- Maximum volumes of 200, 500 and 1000 L
- With or without heating/cooling jackets
- With or without casters

S.U.M. BPC options include:

- Open top liner for media/buffer hydration
- Closed BPC with powder port for contained media/buffer hydration
- Closed BPC with powder port and monitoring probe capability
- Closed BPC for liquid-liquid mixing of critical sterile solutions such as pooling of fractions or processing of intermediate solutions.
- Closed BPC for liquid-liquid mixing with monitoring probe capability.

S.U.M. Recommended Operating Parameters

Temperature	2-40°C
Motor Speed	0-350 rpm
Volume Range	20-100% of Nominal
Maximum Closed Top Mixing Bag Pressure	.2 psig
Continuous Operating Time	21 days*
Maximum Floor Scale Height	3"

*Mixing time at nominal volume only.

Item	Docking Station Frame
Width	34"
Depth	44.8"
Height	61.9"
Weight	509 lbs (231 kg)
Electrical Power Supply Requirement (voltage, phase, amp)	120 or 240 VAC, single, 15 Amp, Non GFCI circuit
Top Stair Height	18.2016"
Programmable VFD, Remote Panel Interface	Standard
Mixer Motor Drive (voltage, phase, amp)	208 VAC, three, 15 Amp
Motor Power Rating	0.5 hp (372.8 W)
Motor Torque Rating	80 lb _f -in (9.04 Nm)
Gear Reduction	5:1

Item	200 L Tank	500 L Tank	1000 L Tank
Rated Liquid Working Volume	200 L	500 L	1000 L
Minimum Liquid Working Volume	40 L	100 L	200 L
BPC Chamber Diameter	20" (50.8 cm)	29.75" (75.6 cm)	41.5" (105.4 cm)
BPC Chamber Shoulder Height	48.6" (123.4 cm)	57.5" (146 cm)	61.9" (157.2 cm)
Liquid Height @ Rated Working Volume	39" (99 cm)	44" (111.8 cm)	45.5" (115.6 cm)
Overall Geometry (height/diameter ratio)	1.95:1	1.5:1	1.1:1
Fluid Geometry @ Working Volume (height/diameter) Ratio	2.2:1	1.7:1	1.2:1
Impeller (quantity x blade count)	1 x 3	1 x 3	1 x 3
Impeller Diameter	7.875" (20 cm)	7.875" (20 cm)	7.875" (20 cm)
Hold-Up Volume (typical)	<50 mL	<100 mL	<300 mL
Skid Width	25.5" (64.8 cm)	30.4" (77 cm)	49.6" (126 cm)
Skid Depth	29" (73.7 cm)	37.4" (95 cm)	49.3" (125.2 cm)
Skid Height	58.2" (147.8 cm)	65.1" (165.3 cm)	63.4" (161 cm)
Dry Skid Weight (mass) Non-Heated Tank	443 lbs (201 kg)	776 lbs (352 kg)	880 lbs (399 kg)
Dry Skid Weight (mass) Jacketed Tank	465 lbs (211 kg)	802 lbs (364 kg)	913 lbs (414 kg)
Wet Skid Weight—Rated Working Volume (mass) Non-Heated Tank	884 lbs (401 kg)	1878 lbs (852 kg)	3084 lbs (1399 kg)
Wet Skid Weight—Rated Working Volume (mass) Jacketed Tank	906 lbs (411 kg)	1905 lbs (864 kg)	3117 lbs (1414 kg)
Minimum Ceiling Height Recommended	10' (305 cm)	11' (335 cm)	11' (335 cm)
Minimum Required Floor Scale Platform Dimensions	23" x 22"	27" x 24"	38" x 38"

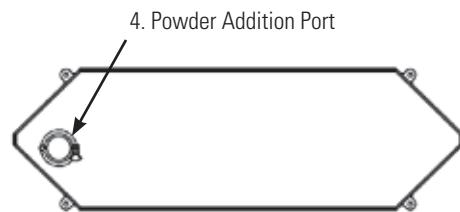


200 L Tank Standard BPC Configurations (CX5-14 Film)

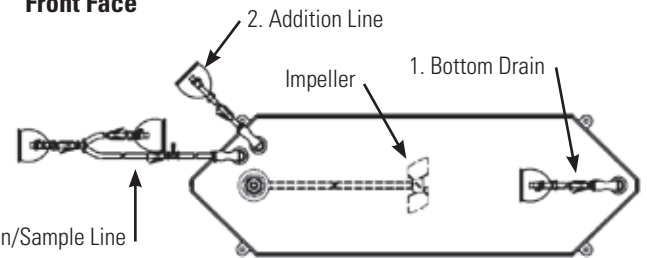
Powder-Liquid Applications—Part number SH30750.01

For use with tubing welder and with CPC® Quick Connects

Back Face



Front Face



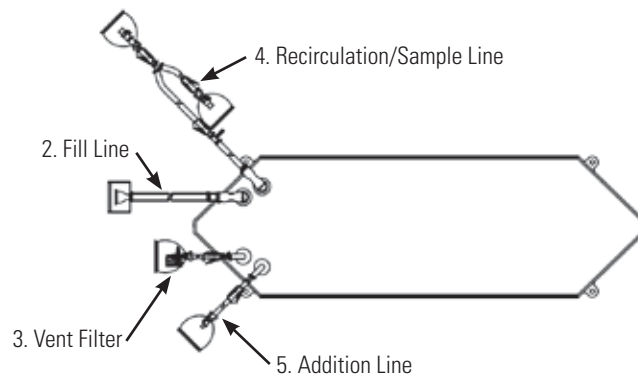
Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex® X 48" (122 cm)	Capped 1/2" (12.7 mm) MPX insert
2	Addition Line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Plugged 1/2" (12.7 mm) MPX body
3	Recirculation/Sample line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 54" (137 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
4	Powder Addition Port	3" (76 mm) Sanitary Fitting, Tri-clamp	Cap with gasket

200 L Tank Standard BPC Configurations (CX5-14 Film)

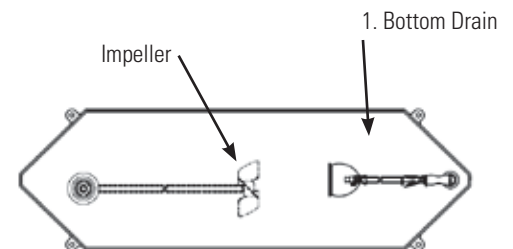
Liquid-Liquid Applications—Part number SH30753.01

For use with tubing welder and with CPC® Quick Connects

Back Face



Front Face



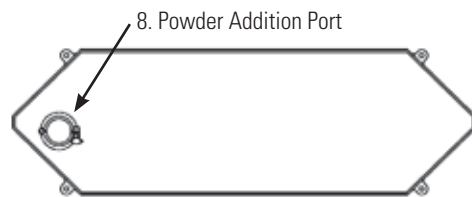
Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Capped 1/2" (12.7 mm) MPX insert
2	Fill Line	3/4" (19.1 mm) ID X 1" (25.4 mm) OD C-Flex X 48" (122 cm)	1 1/2" (38.1 mm) Tri-clamp SterilEnz™
3	Vent Filter	1/4" (6.4 mm) ID X 1/2" (12.7 mm) OD C-Flex X 4" (10.2 cm)	Sterile Hydrophobic Vent Filter (0.2 micron PVDF - Pall Acro 50)
4	Recirculation/Sample Line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 54" (137 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
5	Addition Line	3/8" (9.5 mm) ID X 5/8" (15.9 mm) OD C-Flex X 24" (61 cm)	Plugged 3/8" (9.5 mm) MPX body

200 L Tank Standard BPC Configurations (CX5-14 Film)

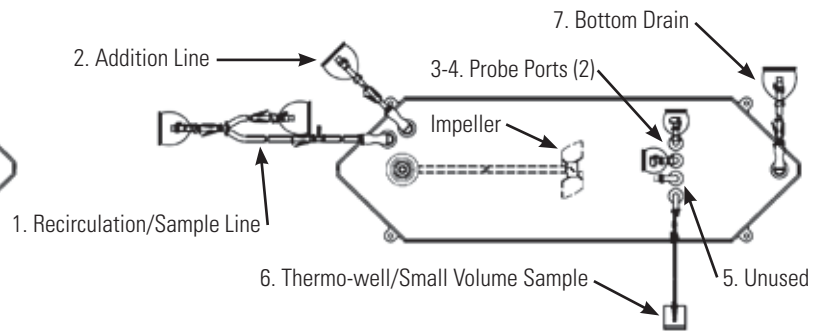
Powder-Liquid Applications with Probe Ports and Thermo-well—Part number SH30750.02

For use with tubing welder and with CPC® Quick Connects

Back Face



Front Face



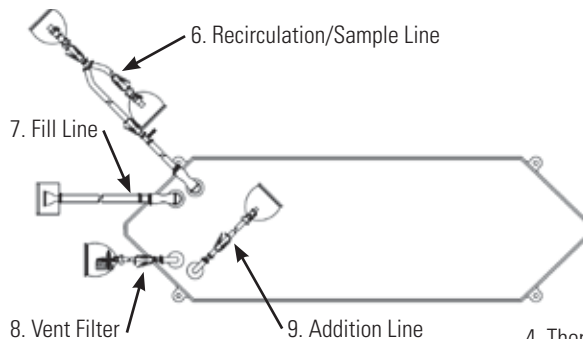
Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Recirculation/Sample line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 54" (137 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
2	Addition Line	1/2" (12.7 mm) ID X 5/8" (15.9 mm) OD C-Flex X 48" (122 cm)	Plugged 1/2" (12.7 mm) MPX body
3-4	Probe Ports (2)	None	Pall™ Kleenpak™ Aseptic Connector KPCHT Series (Female)
5	Unused	None	Plug
6	Thermo-well/ Small Volume Sample	Thermo-well Adapter for 1/8" (3.2 mm) Diameter 1/8" (3.2 mm) ID X 1/4" (6.4 mm) OD C-Flex X 12" (30 cm)	Luer and SmartSite® Valve Port
7	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Plugged 1/2" (12.7 mm) MPX body
8	Powder Addition Port	3" (76 mm) Sanitary Fitting, Tri-clamp	Cap with gasket

200 L Tank Standard BPC Configurations (CX5-14 Film)

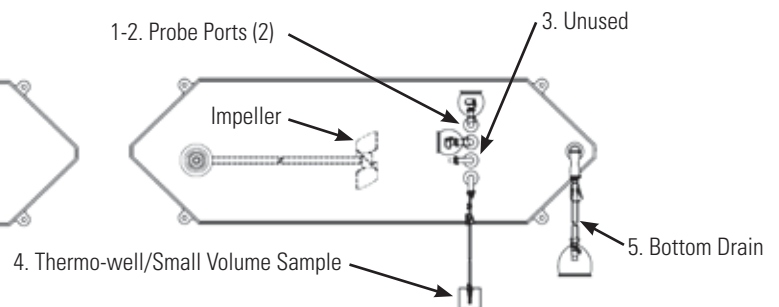
Liquid-Liquid Applications with Probe Ports and Thermo-well—Part number SH30753.02

For use with tubing welder and with CPC® Quick Connects

Back Face



Front Face



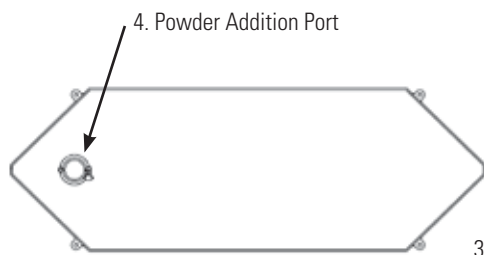
Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1-2	Probes Ports (2)	None	Pall Kleenpak Aseptic Connector KPCHT Series (Female)
3	Unused	None	Plug
4	Thermo-well/ Small Volume Sample	Thermo-well Adapter for 1/8" (3.2 mm) Diameter 1/8" (3.2 mm) ID X 1/4" (6.4 mm) OD C-Flex X 12" (30 cm)	Luer and SmartSite Valve Port
5	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Capped 1/2" (1.27 cm) MPX insert
6	Recirculation/Sample Line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
7	Fill Line	3/4" (19.1 mm) ID X 1" (25.4 mm) OD C-Flex X 48" (122 cm)	1 1/2" Tri-clamp SterilEnz
8	Vent Filter	1/4" (6.4 mm) ID X 1/2" (12.7 mm) OD C-Flex X 4" (10.2 cm)	Sterile Hydrophobic Vent Filter (0.2 micron PVDF - Pall Acro 50)
9	Addition Line	3/8" (9.5 mm) ID X 5/8" (15.9 mm) OD C-Flex X 24" (61 cm)	Plugged 3/8" (9.5 mm) MPX body

500 L Tank Standard BPC Configurations (CX5-14 Film)

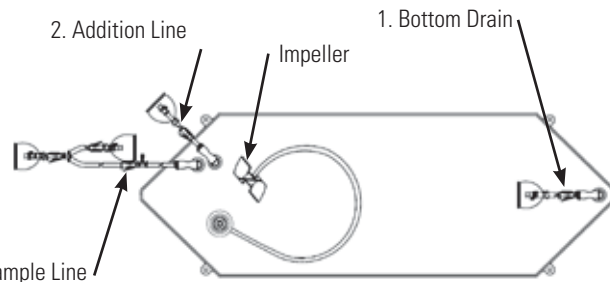
Powder-Liquid Applications—Part number SH30751.01

For use with tubing welder and with CPC® Quick Connects

Back Face



Front Face



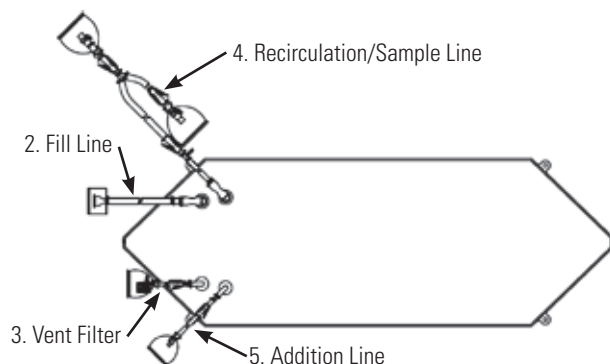
Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex® X 48" (122 cm)	Capped 1/2" (12.7 mm) MPX insert
2	Addition Line	1/2" (12.7 mm) ID X 5/8" (15.9 mm) OD C-Flex X 60" (152 cm)	Plugged 1/2" (12.7 mm) MPX body
3	Recirculation/Sample Line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 66" (168 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
4	Powder Addition Port	3" (76 mm) Sanitary Fitting, Tri-clamp	Cap with gasket

500 L Tank Standard BPC Configurations (CX5-14 Film)

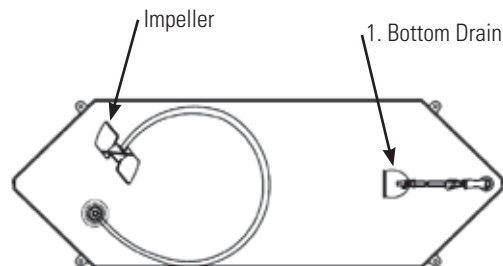
Liquid-Liquid Applications—Part number SH30754.01

For use with tubing welder and with CPC® Quick Connects

Back Face



Front Face

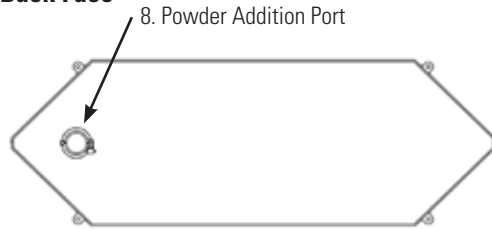


Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Capped 1/2" (12.7 mm) MPX insert
2	Fill Line	3/4" (19.1 mm) ID X 1" (25.4 mm) OD C-Flex X 60" (152 cm)	1 1/2" (38.1 mm) Tri-clamp SterilEnz™
3	Vent Filter	1/4" (6.4 mm) ID X 1/2" (12.7 mm) OD C-Flex X 4" (10.2 cm)	Sterile Hydrophobic Vent Filter (0.2 micron PVDF - Pall Acro 50)
4	Recirculation/Sample Line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 66" (168 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
5	Addition Line	3/8" (9.5 mm) ID X 5/8" (15.9 mm) OD C-Flex X 24" (61 cm)	Plugged 3/8" (9.5 mm) MPX body

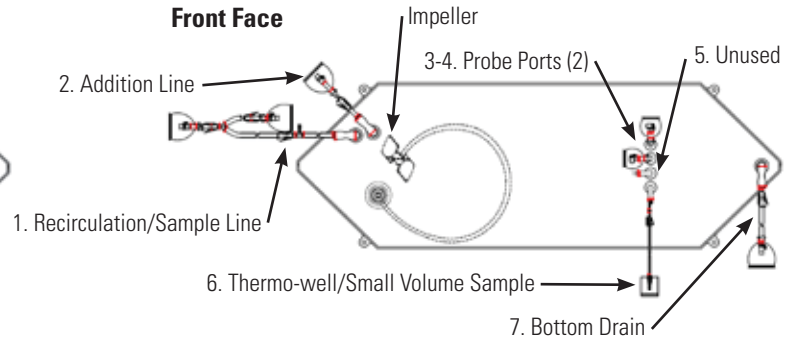
500 L Tank Standard BPC Configurations (CX5-14 Film)

Powder-Liquid Applications with Probe Ports and Thermo-well—Part number SH30751.02
For use with tubing welder and with CPC® Quick Connects

Back Face



Front Face

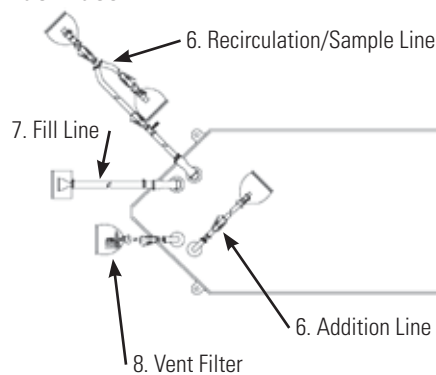


Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Recirculation/Sample line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 66" (168 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
2	Addition Line	1/2" (12.7 mm) ID X 5/8" (15.9 mm) OD C-Flex X 60" (152 cm)	Plugged 1/2" (12.7 mm) MPX body
3-4	Probe Ports (2)	None	Pall™ Kleenpak™ Aseptic Connector KPCHT Series (Female)
5	Unused	None	Plug
6	Thermo-well/ Small Volume Sample	Thermo-well Adapter for 1/8" (3.2 mm) Diameter 1/8" (3.2 mm) ID X 1/4" (6.4 mm) OD C-Flex X 12" (30 cm)	Luer and SmartSite® Valve Port
7	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Plugged 1/2" (12.7 mm) MPX body
8	Powder Addition Port	3" (76 mm) Sanitary Fitting, Tri-clamp	Cap with gasket

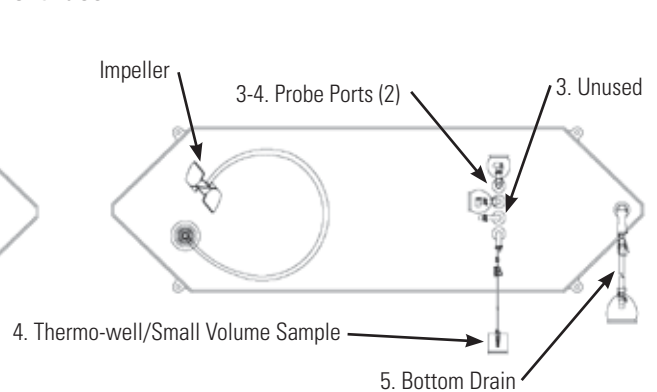
500 L Tank Standard BPC Configurations (CX5-14 Film)

Liquid-Liquid Applications with Probe Ports and Thermo-well—Part number SH30754.02
For use with tubing welder and with CPC® Quick Connects

Back Face



Front Face



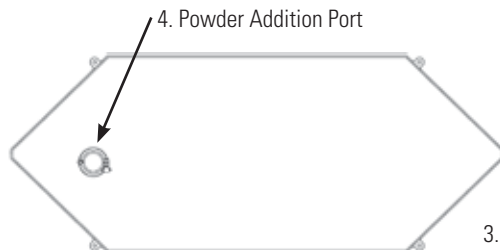
Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1-2	Probe Ports (2)	None	Pall Kleenpak Aseptic Connector KPCHT Series (Female)
3	Unused	None	Plug
4	Thermo-well/ Small Volume Sample	Thermo-well Adapter for 1/8" (3.2 mm) Diameter 1/8" (3.2 mm) ID X 1/4" (6.4 mm) OD C-Flex X 12" (30 cm)	Luer and SmartSite Valve Port
5	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Capped 1/2" (1.27 cm) MPX insert
6	Recirculation/Sample line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 66" (168 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
7	Fill Line	3/4" (19.1 mm) ID X 1" (25.4 mm) OD C-Flex X 60" (152 cm)	1 1/2" Tri-clamp SterilEnz
8	Vent Filter	1/4" (6.4 mm) ID X 1/2" (12.7 mm) OD C-Flex X 4" (10.2 cm)	Sterile Hydrophobic Vent Filter (0.2 micron PVDF - Pall Acro 50)
9	Addition Line	3/8" (9.5 mm) ID X 5/8" (15.9 mm) OD C-Flex X 24" (61 cm)	Plugged 3/8" (9.5 mm) MPX body

1000 L Tank Standard BPC Configurations (CX5-14 Film)

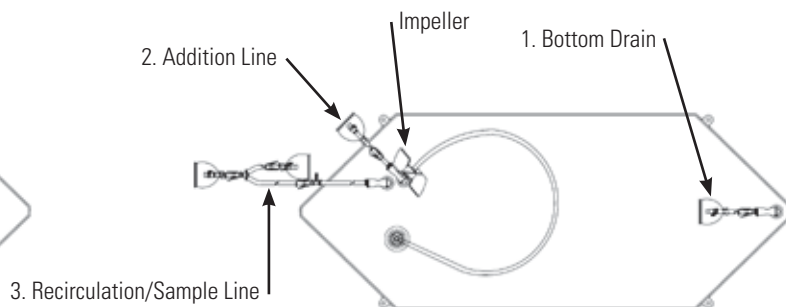
Powder-Liquid Applications—Part number SH30752.01

For use with tubing welder and with CPC® Quick Connects

Back Face



Front Face



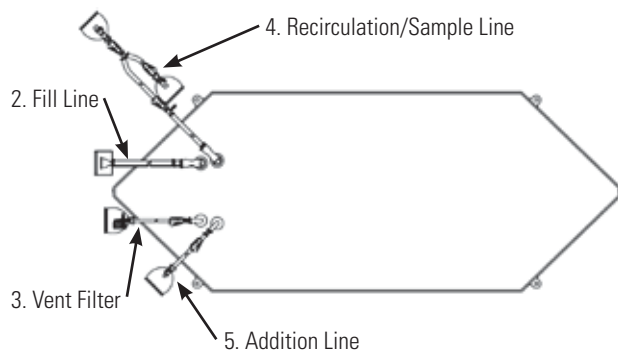
Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex® X 48" (122 cm)	Capped 1/2" (12.7 mm) MPX insert
2	Addition Line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 72" (183 cm)	Plugged 1/2" (12.7 mm) MPX body
3	Recirculation/Sample line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 78" (198 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
4	Powder Addition Port	3" (76 mm) Sanitary Fitting, Tri-clamp	Cap with gasket

1000 L Tank Standard BPC Configurations (CX5-14 Film)

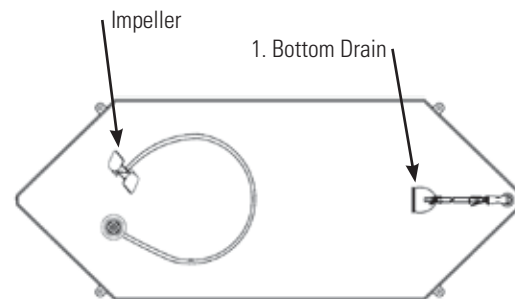
Liquid-Liquid Applications—Part number SH30755.01

For use with tubing welder and with CPC® Quick Connects

Back Face



Front Face

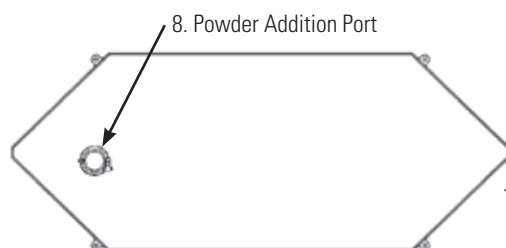


Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Capped 1/2" (12.7 mm) MPX insert
2	Fill Line	3/4" (19.1 mm) ID X 1" (25.4 mm) OD C-Flex X 72" (183 cm)	1 1/2" (38.1 mm) Tri-clamp SterilEnz™
3	Vent Filter	1/4" (6.4 mm) ID X 1/2" (12.7 mm) OD C-Flex X 4" (10.2 cm)	Sterile Hydrophobic Vent Filter (0.2 micron PVDF - Pall Acro 50)
4	Recirculation/Sample line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 78" (198 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
5	Addition Line	3/8" (9.5 mm) ID X 5/8" (15.9 mm) OD C-Flex X 24" (61 cm)	Plugged 3/8" (9.5 mm) MPX body

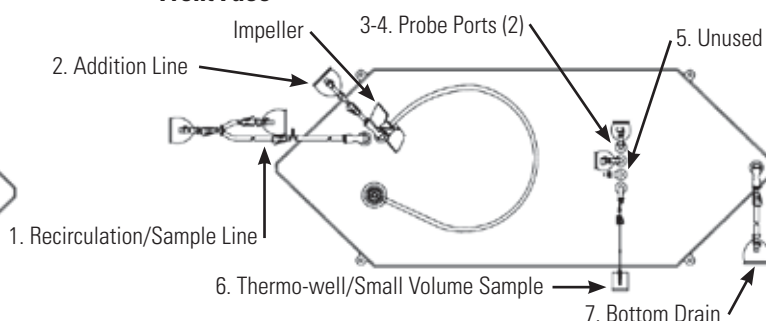
1000 L Tank Standard BPC Configurations (CX5-14 Film)

Powder-Liquid Applications with Probe Ports and Thermo-well—Part number SH30752.02
For use with tubing welder and with CPC® Quick Connects

Back Face



Front Face

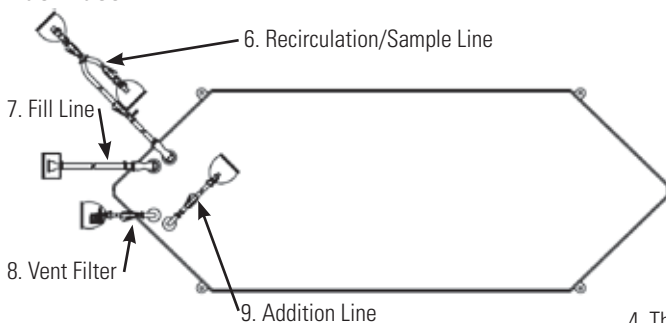


Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1	Recirculation/Sample Line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 78" (198 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
2	Addition Line	1/2" (12.7 mm) ID X 5/8" (15.9 mm) OD C-Flex X 48" (122 cm)	Plugged 1/2" (12.7 mm) MPX body
3-4	Probe Ports (2)	None	Pall™ Kleenpak™ Aseptic Connector KPCHT Series (Female)
5	Unused	None	Plug
6	Thermo-well/ Small Volume Sample	Thermo-well Adapter for 1/8" (3.2 mm) Diameter 1/8" (3.2 mm) ID X 1/4" (6.4 mm) OD C-Flex X 12" (30 cm)	Luer and SmartSite® Valve Port
7	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Plugged 1/2" (12.7 mm) MPX body
8	Powder Addition Port	3" (76 mm) Sanitary Fitting, Tri-clamp	Cap with gasket

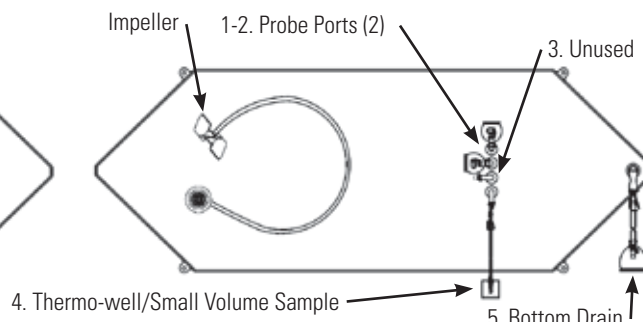
1000 L Tank Standard BPC Configurations (CX5-14 Film)

Liquid-Liquid Applications with Probe Ports and Thermo-well—Part number SH30755.02
For use with tubing welder and with CPC® Quick Connects

Back Face



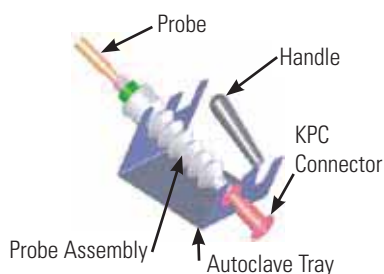
Front Face



Line	Description	Tubing Set (ID X OD X Length)	End Treatment
1-2	Probe Ports (2)	None	Pall Kleenpak Aseptic Connector KPCHT Series (Female)
3	Unused	None	Plug
4	Thermo-well/ Small Volume Sample	Thermo-well Adapter for 1/8" (3.2 mm) Diameter 1/8" (3.2 mm) ID X 1/4" (6.4 mm) OD C-Flex X 12" (30 cm)	Luer and SmartSite Valve Port
5	Bottom Drain	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 48" (122 cm)	Capped 1/2" (1.27 cm) MPX insert
6	Recirculation/Sample line	1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 78" (198 cm) splits to 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 24" (61 cm) and 1/2" (12.7 mm) ID X 3/4" (19.1 mm) OD C-Flex X 12" (30 cm)	Capped 1/2" (12.7 mm) MPX insert Plugged 1/2" (12.7 mm) MPX body
7	Fill Line	3/4" (19.1 mm) ID X 1" (25.4 mm) OD C-Flex X 72" (183 cm)	1 1/2" Tri-clamp SterilEnz
8	Vent Filter	1/4" (6.4 mm) ID X 1/2" (12.7 mm) OD C-Flex X 4" (10.2 cm)	Sterile Hydrophobic Vent Filter (0.2 micron PVDF - Pall Acro 50)
9	Addition Line	3/8" (9.5 mm) ID X 5/8" (15.9 mm) OD C-Flex X 24" (61 cm)	Plugged 3/8" (9.5 mm) MPX body

Ordering Information for Standard Products

Autoclave Tray and Probe Kits:



Additional Information on Autoclave Tray:

- Fabricated from stainless steel
- Plastic carry handle for easy transport right out of the autoclave
- Positions probes on 15% incline for greater probe/membrane longevity
- Will restrain probe bellows from collapsing during sterilization
- Probe holder accommodates two probes

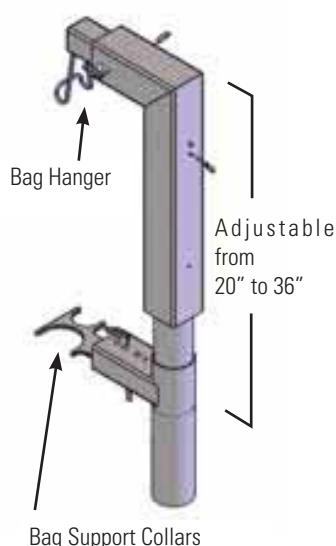
Probe Holders (Clips):

Standard probes can be used with docking tanks by employing probe assemblies and probe holders. The holders are retained in position by the probe holder band above the probe window on the tank hatch.



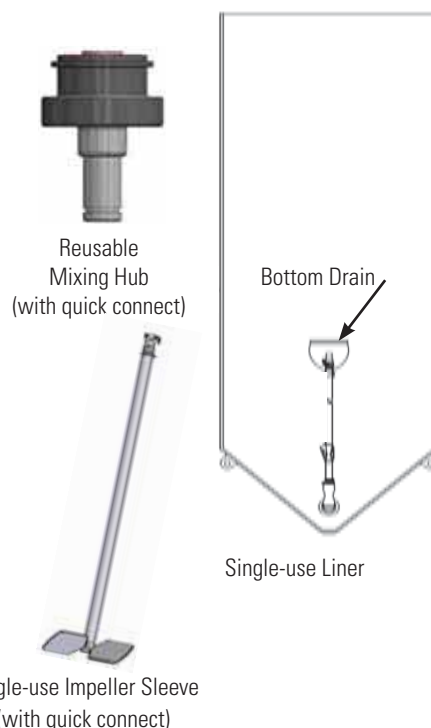
Powdertainer Hanger:

The Single-Use Mixer (S.U.M.) can be equipped with a Thermo Scientific HyClone Powdertainer Hanger if so desired. When adding solids to liquids, this optional feature enables utilization of the Powdertainer powder feed system. The Powdertainer hanger can be used to support full 1, 5 or 25 Kg Powdertainers and one collar positions the 3" sanitary connectors for bag-to-bag connection and solids transfer. The second collar is provided to support the bearing hub assembly when the tank is detached from the docking station motor.



Open-Top Mixing (OTM) use:

The S.U.M. can be equipped with a reusable mixing hub accessory to enable use of open top liners and single-use impeller sleeves. The OTM option is a non-sterile easy-to-use mixing option. The reusable hub is simply placed into the motor's bearing port receiver and latched into place. The single-use impeller sleeve attaches to the hub's quick connect end. With an open liner in position and a drive shaft inserted the system is ready to use.



Accessories

Part Number	Description	
SH30720.01	Probe Assembly (non-sterile)	Used to package probes (not supplied) for sterilization and to aseptically connect them to the S.U.M. BPC.
SV20664.01	Heavy Duty Tubing Clamp	Reusable tubing clamp used on probe ports when connecting probe assembly.
SV20664.02	Heavy Duty Tubing Clamp (4 pack of SV20664.01)	
SV20664.03	Heavy Duty Tubing Clamp (10 pack of SV20664.01)	
SV20750.01	S.U.M. thermo-well/sample port	Used for RTD calibration/validation.
SV20778.01	RTD	Pt100 Resistance Temperature Detector for use with S.U.M BPC thermo-well/sampling port.
SV50177.01	Autoclave Tray for Probe Kits (stainless steel)	Support tray which allows the probes to be safely autoclaved.
SH30845.01	Sterile Sampling Manifold with luer lock (individual)	Available for aseptic luer connection or welding onto the sample line to take sample sets.
SH30845.02	Sterile Sampling Manifold with luer lock (10 pack)	
SV50187.05	Powdertainer Hanger with Dual Support Collars	To support Powdertainer and Bearing Port (for bag use in Docking Tanks)
SV50177.77	Reusable Mixing Hub	Required for use with single-use impeller sleeve
SH30762.01	200 L Liner for S.U.M. (gamma-sterilized), Open Top Mixing	Bottom drain liner with 72" (182.9 cm) of ½" (12.7 mm) C-Flex tubing and an MPX insert connector, CX3-9 Film
SH30762.02	500 L Liner for S.U.M. (gamma-sterilized), Open Top Mixing	Bottom drain liner with 72" (182.9 cm) of ½" (12.7 mm) C-Flex tubing and an MPX insert connector, CX3-9 Film
SH30762.03	1000 L Liner for S.U.M. (gamma-sterilized), Open Top Mixing	Bottom drain liner with 72" (182.9 cm) of ½" (12.7 mm) C-Flex tubing and an MPX insert connector, CX3-9 Film
SH30749.08	Single-use Impeller Sleeve for 200 L tanks	For Open-Top Mixing
SH30749.10	Single-use Impeller Sleeve for 500 and 1000 L tanks	For Open-Top Mixing

Hardware Standard Products

Part Number	Description	
SV50222.01	S.U.M. Docking Station System (120 VAC, Single Phase)	Includes: 304 stainless steel cart with swivel casters, adjustable motor mounting, motor, variable speed agitation speed controller, drive assembly, shaft, steps and standard tool set.
SV50222.02	S.U.M. Docking Station System (240 VAC, Single Phase)	Includes: 304 stainless steel cart with swivel casters, adjustable motor mounting, motor, variable speed agitation speed controller, drive assembly, shaft, steps and standard tool set.
SV50224.01	200 L S.U.M. Docking Station Tank, non-jacketed, feet	Includes: 304 stainless steel outer support container with platform on feet.
SV50224.02	200 L S.U.M. Docking Station Tank, non-jacketed, casters	Includes: 304 stainless steel outer support container with platform on swivel casters.
SV50224.03	200 L S.U.M. Docking Station Tank, jacketed, feet	Includes: 304 stainless steel outer support container with heating/cooling jacket and platform on feet.
SV50224.04	200 L S.U.M. Docking Station Tank, jacketed, casters	Includes: 304 stainless steel outer support container with heating/cooling jacket and platform on swivel casters.
SV50225.01	500 L S.U.M. Docking Station Tank, non-jacketed, feet	Includes: 304 stainless steel outer support container with platform on feet.
SV50225.02	500 L S.U.M. Docking Station Tank, non-jacketed, casters	Includes: 304 stainless steel outer support container with platform on swivel casters.
SV50225.03	500 L S.U.M. Docking Station Tank, jacketed, feet	Includes: 304 stainless steel outer support container with heating/cooling jacket and platform on feet.
SV50225.04	500 L S.U.M. Docking Station Tank, jacketed, casters	Includes: 304 stainless steel outer support container with heating/cooling jacket and platform on swivel casters.
SV50226.01	1000 L S.U.M. Docking Station Tank, non-jacketed, feet	Includes: 304 stainless steel outer support container with platform on feet.
SV50226.02	1000 L S.U.M. Docking Station Tank, non-jacketed, casters	Includes: 304 stainless steel outer support container with platform on swivel casters.
SV50226.03	1000 L S.U.M. Docking Station Tank, jacketed, feet	Includes: 304 stainless steel outer support container with heating/cooling jacket and platform on feet.
SV50226.04	1000 L S.U.M. Docking Station Tank, jacketed, casters	Includes: 304 stainless steel outer support container with heating/cooling jacket and platform on swivel casters.

Custom BPC Options:

Tubing Type	C-Flex (clear, white, and ADCF), Silicone, PVC, PharMed® or PharmaPure®
Tubing Size	Specific Lengths of 1/8 to 1" (3.18 to 25.4 mm) ID — depending on type of tubing chosen
Connectors	Luer — 1/8 to 1/2" (3.18 to 12.7 mm) ID CPC — 1/4 to 3/4" (6.35 to 19 mm) ID SIP Connector — 1/4 to 3/4" (6.35 to 19 mm) ID Tri-clamp — 1/8" to 1" (3.18 to 25.4mm) ID Mini-Tri-clamp — 1/8 to 1/2" (6.35 to 12.7 mm) ID Aseptic Connection Device — All available sizes of Pall Kleenpak and BioQuate™ DAC
Others	Needle-free sample port (SmartSite or Clave®) Filter Capsule (Millipore®, Pall, Sartorius™, Domnick Hunter®, Meissner®, Other)

Please Note: Not all options are available for all ports. Customization of port type and location, chamber dimensions or mixing assembly is not available. For additional information, please refer to the Selection Guides in the 2008 BPC Catalog.

Presentation (as dry BPC systems):

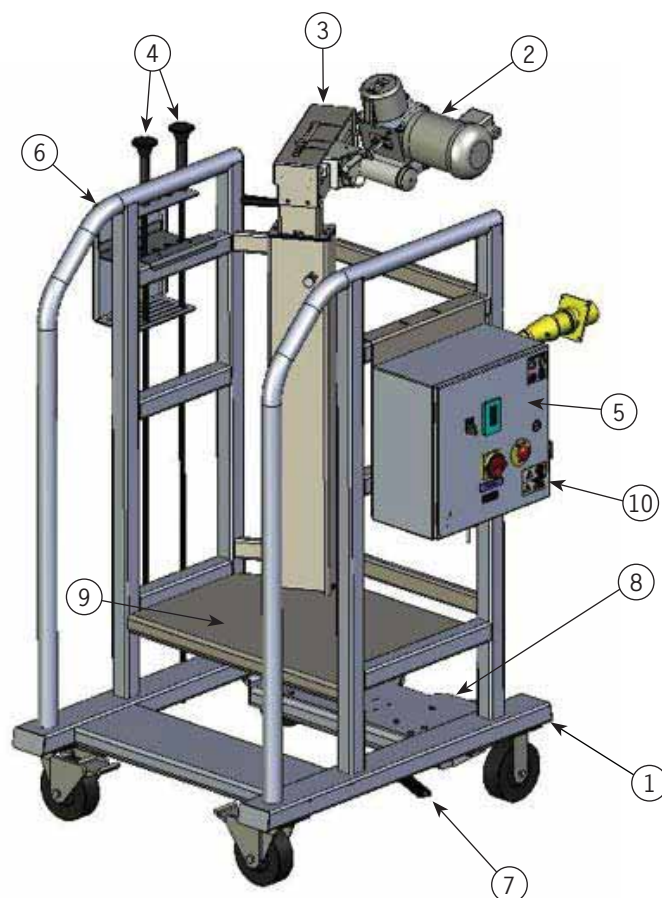
Outer Packaging	Supplied 'flat-packed' Two polyethylene outer layers
Label	Description Product code Lot number Expiry date on outer packaging and shipping container
Sterilization	Irradiation (25 to 38 kGy) inside outer packaging
Shipping Container	Durable cardboard carton
Documentation	Certificate of Analysis provided with each lot for each delivery

Hardware Features

S.U.M. Docking Station System

Docking Station – including the following features:

1. Platform with large diameter wheels
2. Mixer motor
3. Motor adjustment mechanism
4. Drive shafts
5. Control panel
6. Tool kit
7. Docking lock lever
8. Docking lock mechanism (grapple)
9. Step
10. ID plate

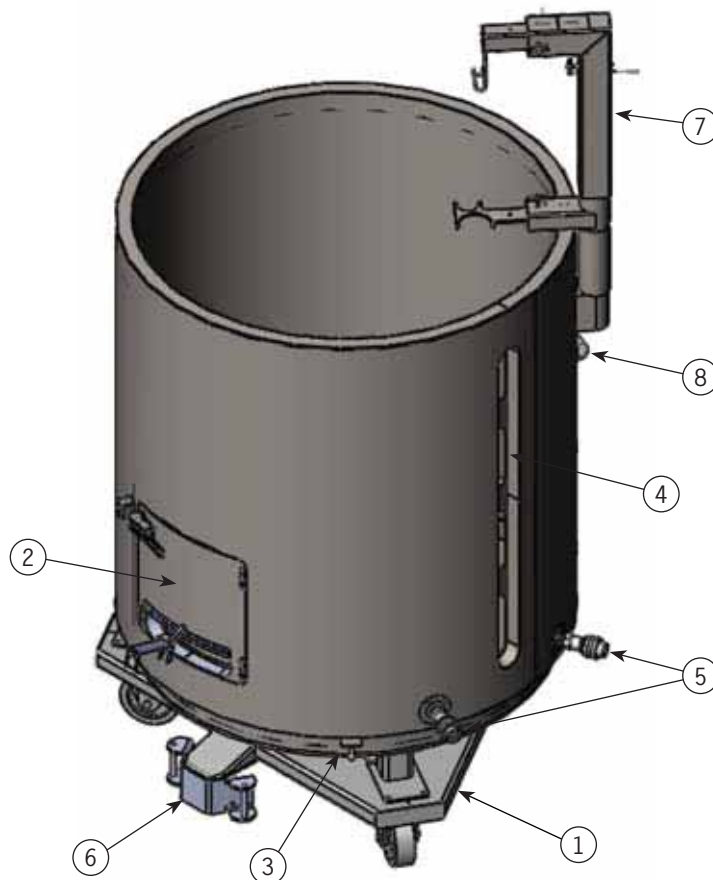


S.U.M. Docking Station System

Docking Station Tank (Jacketed version shown)

– including the following features:

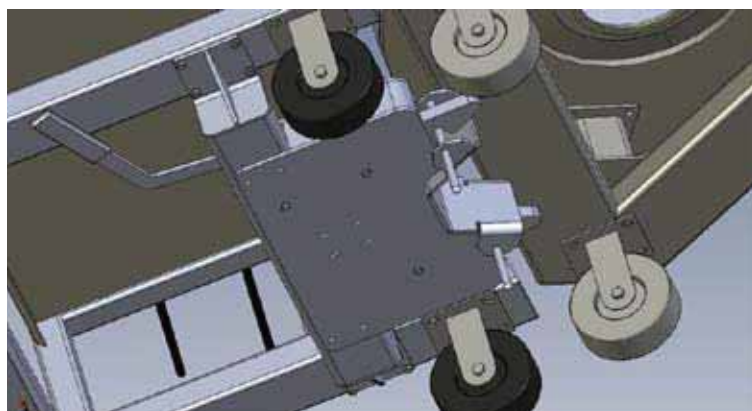
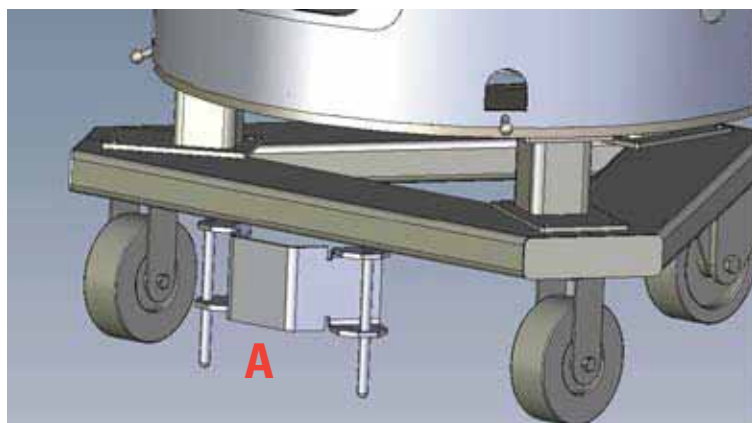
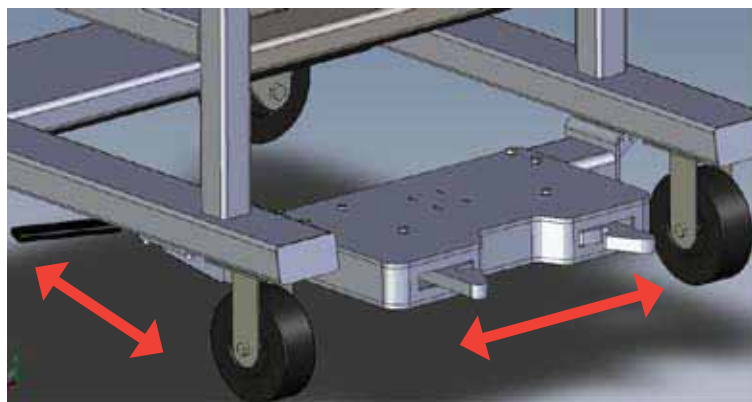
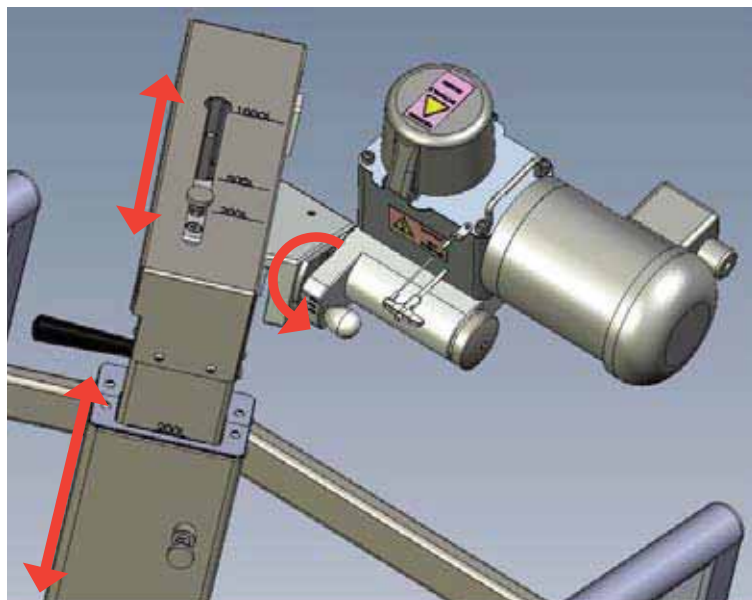
1. Platform with large diameter wheels (available with feet)
2. One of two hatches for BPC loading and monitoring probe insertion
3. Bottom cut outs for BPC alignment
4. Sight window
5. Inlet/outlet for temperature control fluid (jacketed version only)
6. Grapple receiver
7. Support arm for Powdertainer (optional extra)
8. Handle to assist with tank mobility



Operation of S.U.M. Docking Station

The design features which enable the S.U.M. Docking Station hardware to link up with the 200, 500 and 1000 L tanks are as follows:

1. The mixer motor mounting is adjustable vertically and horizontally as shown to the right. In addition the motor angle is adjustable. The adjustments are simple to make with indicators showing the correct setting for each size of tank and secure locking mechanism. Adjustments are made before the S.U.M. BPC is loaded into the tank
2. The S.U.M. Docking Station and tanks are mounted on lockable casters to enable mobility and accurate positioning
3. Locking jaws (or grapple) which open and close horizontally are controlled by a lever on the side of the hardware
4. Each S.U.M. docking station tank has a grapple receiver (A) onto which the jaws lock to secure the tank in the correct orientation to the docking station.
5. Once the tank is locked in place (as shown from underneath) the S.U.M. BPC can be loaded and used in the same way as with other S.U.M. systems.

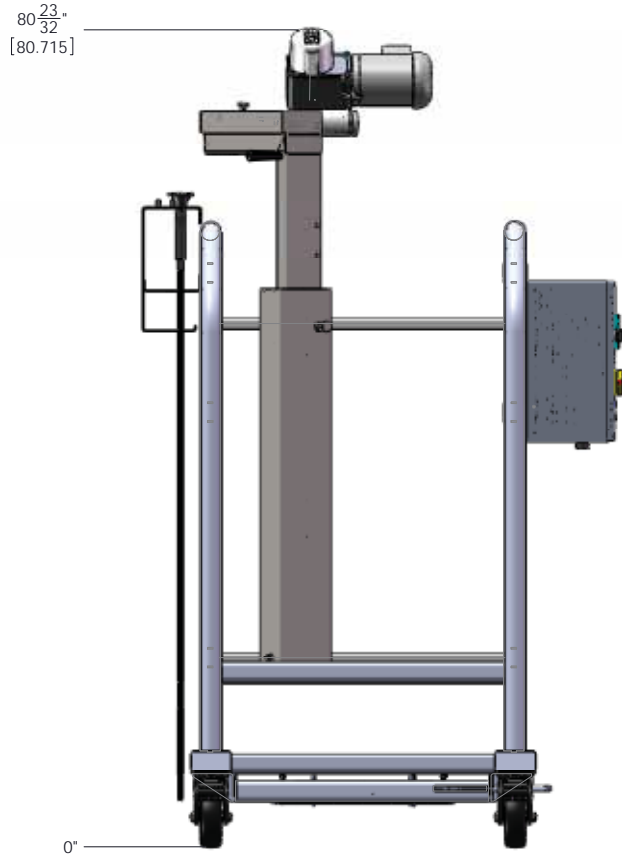


Hardware Dimensions (units in inches [mm])

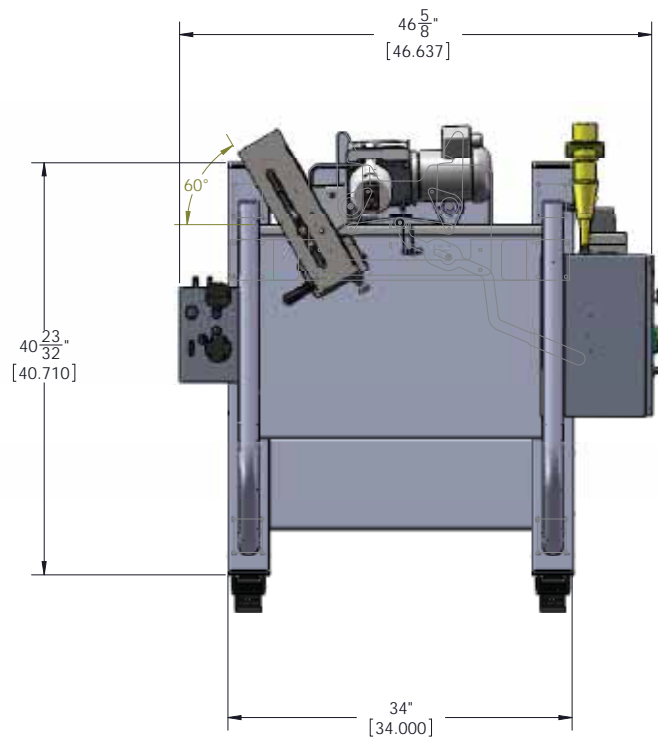
Docking Station:

Front View

(Maximum height – adjusted for 1000 L tank)

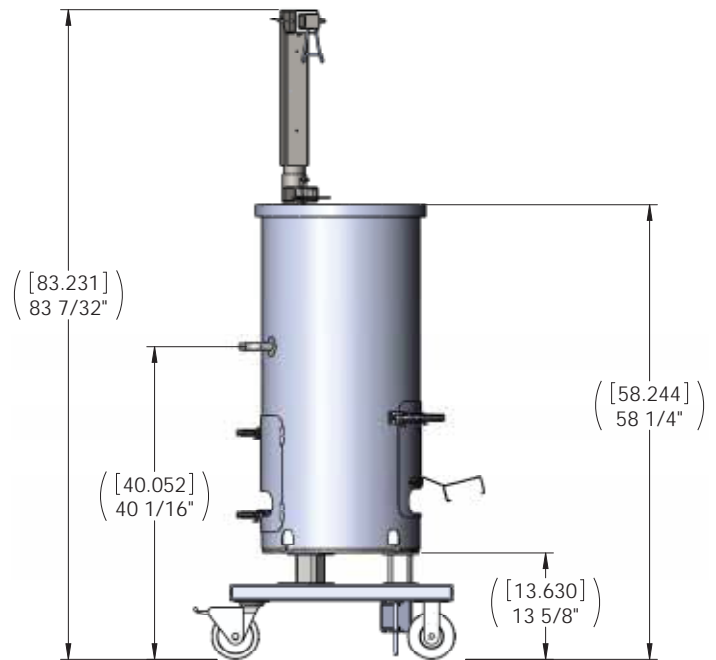
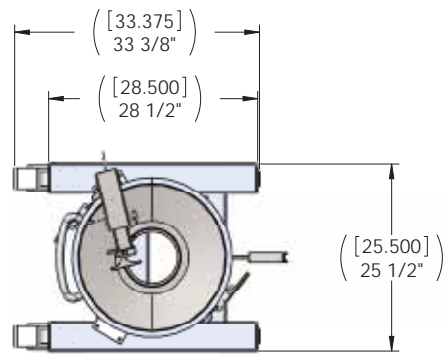


Overhead View

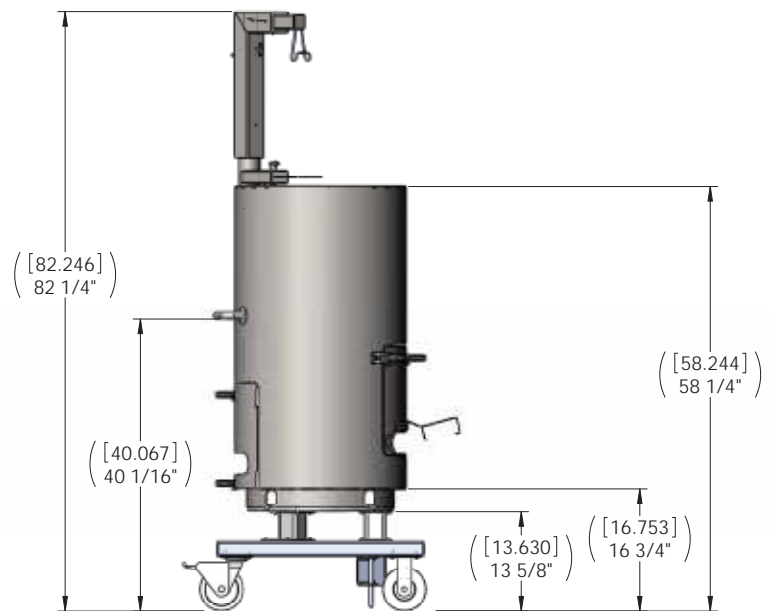
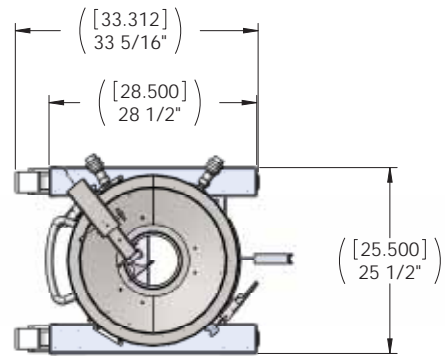


Hardware Dimensions (units in inches [mm])

200 L Non-Jacketed S.U.M.:

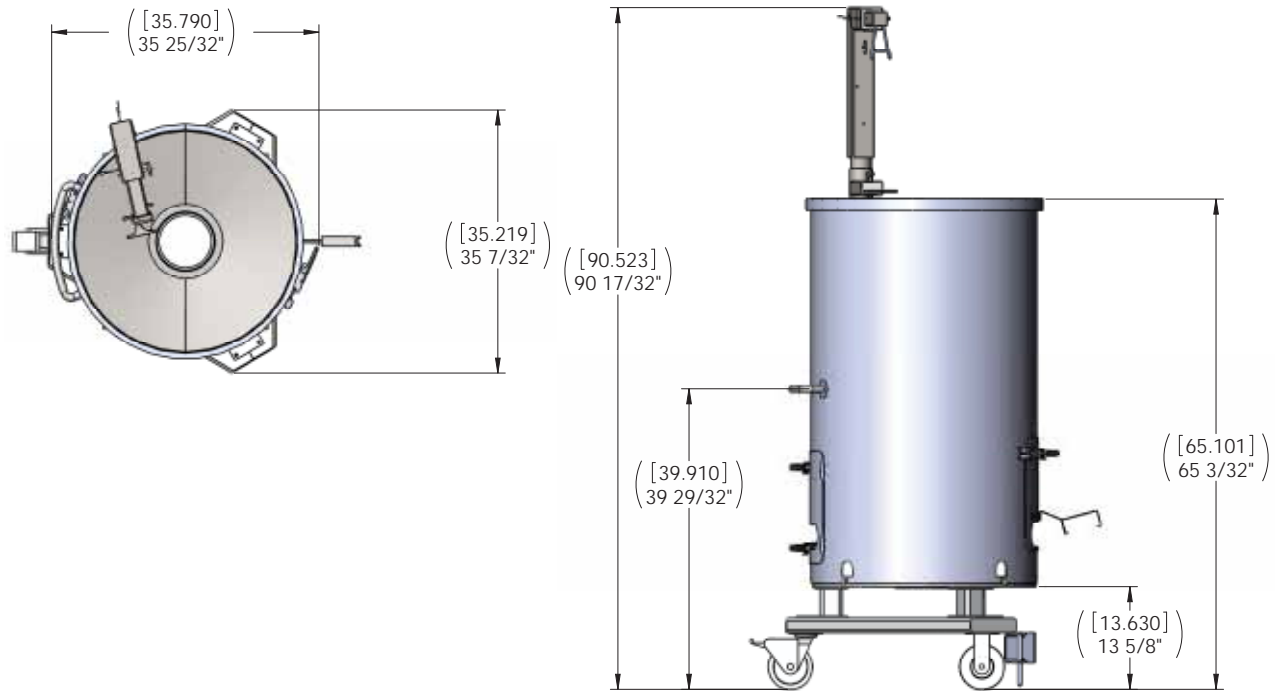


200 L Jacketed S.U.M.:

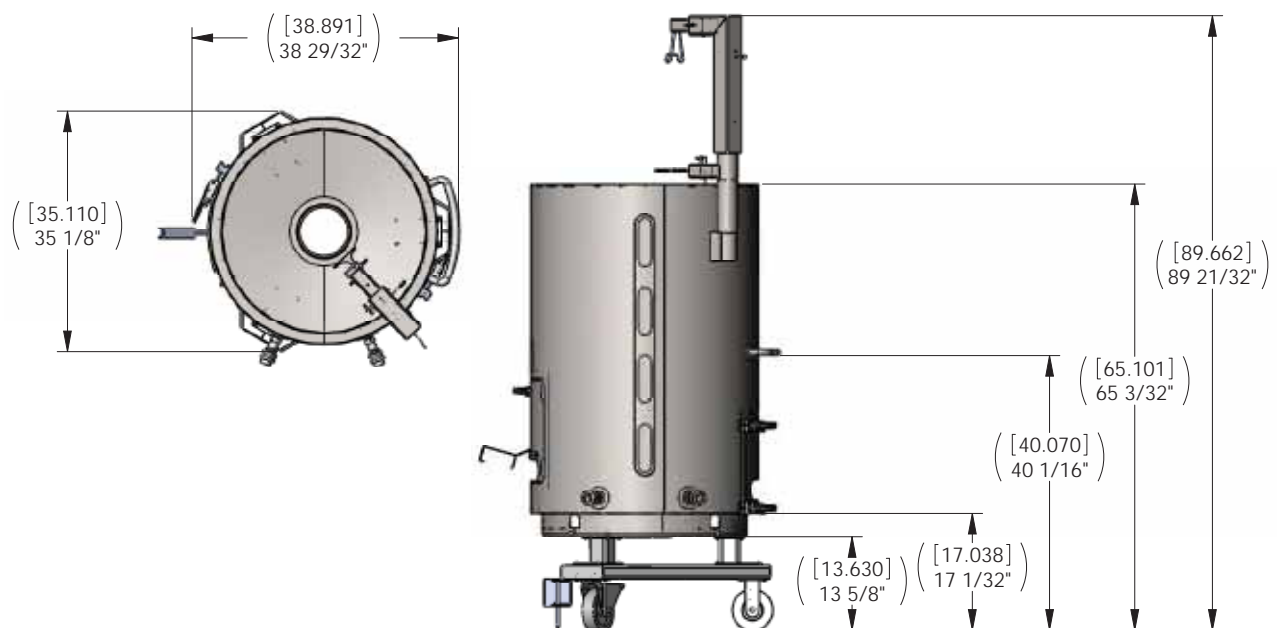


Hardware Dimensions (units in inches [mm])

500 L Non-Jacketed S.U.M.:

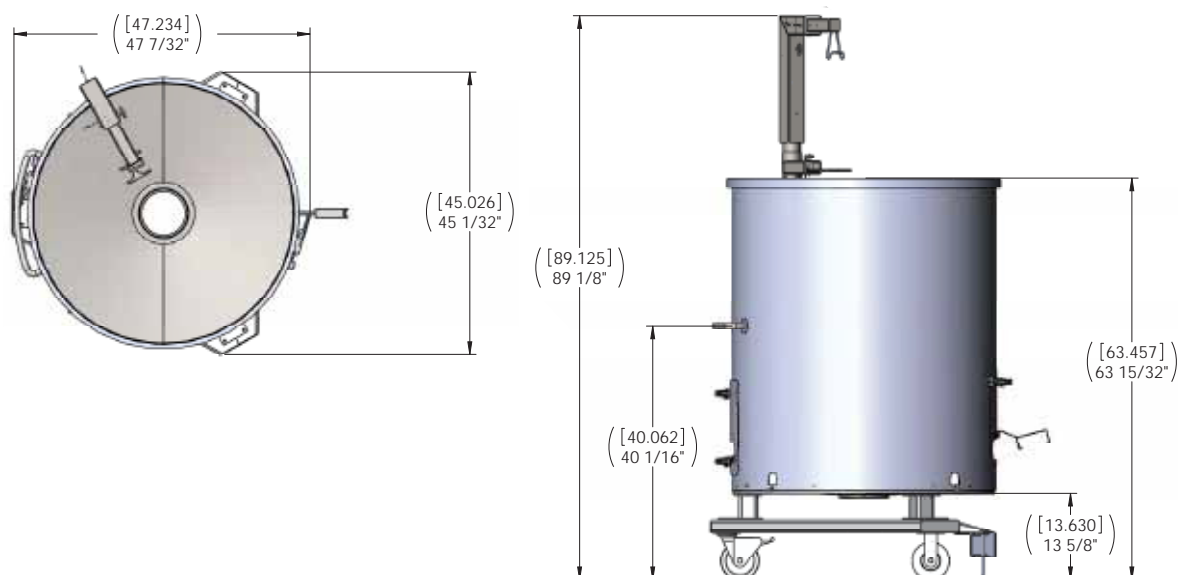


500 L Jacketed S.U.M.:

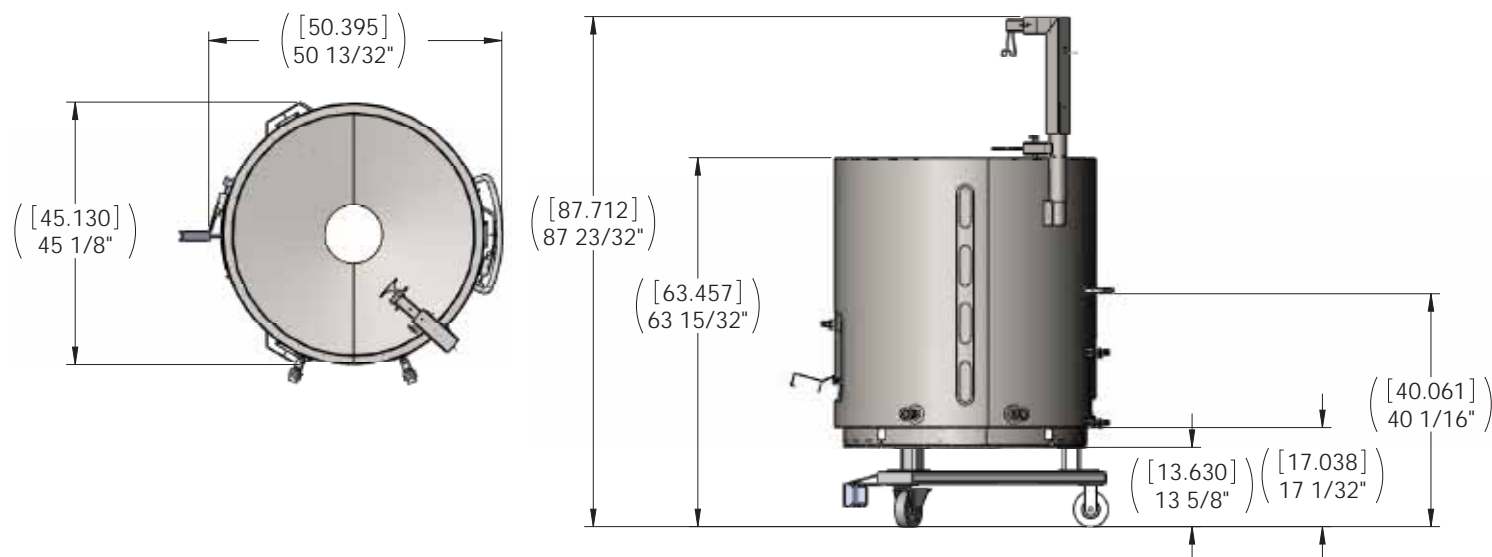


Hardware Dimensions (units in inches [mm])

1000 L Non-Jacketed S.U.M.:



1000 L Jacketed S.U.M.:



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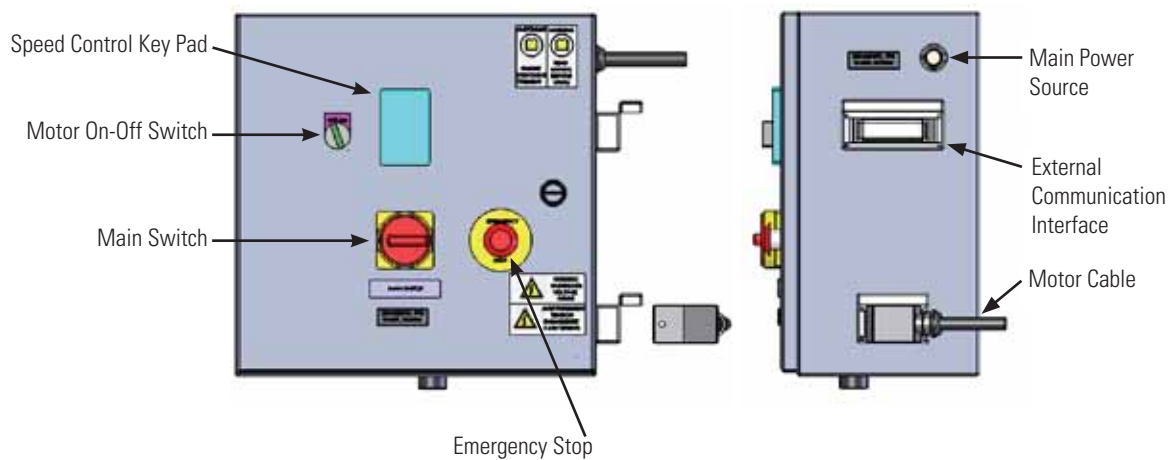
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3.6.2 Docking Station Frame and Tank Specifications

Docking Station Frame	Width	34"
	Depth	44.8"
	Height	61.9"
	Weight	509 lbs (231 kg)
	Electrical Power Supply Requirement (voltage, phase, amp)	120 or 240 VAC, single, 15 Amp Non GFCI circuit
	Top Stair Height	18.2016"
	Programmable VFD, Remote Panel Interface	standard
	Mixer Motor Drive (voltage, phase, amp)	208 VAC, three, 15 Amp
	Motor Power Rating	0.5 hp (372.8 W)
	Motor Torque Rating	80 lb _f -in (9.04 Nm)
	Gear Reduction	5:1
200 L Tank	Rated Liquid Working Volume	200 L
	Minimum Liquid Working Volume	40 L
	BPC Chamber Diameter	20" (50.8 cm)
	BPC Chamber Shoulder Height	48.6" (123.4 cm)
	Liquid Height @ Rated Working Volume	39" (99 cm)
	Overall Geometry (height/diameter ratio)	1.95:1
	Fluid Geometry @ Working Volume (height/diameter) Ratio	2.2:1
	Impeller (quantity x blade count)	1 x 3
	Impeller Diameter	7.875" (20 cm)
	Hold-Up Volume (typical)	<50 mL
	Skid Width	25.5" (64.8 cm)
	Skid Depth	29" (73.7 cm)
	Skid Height	58.2" (147.8 cm)
	Dry Skid Weight (mass) Non-Heated Tank	443 lbs (201 kg)
	Dry Skid Weight (mass) Jacketed Tank	465 lbs (211 kg)
	Wet Skid Weight—Rated Working Volume (mass) Non-Heated Tank	884 lbs (401 kg)
	Wet Skid Weight—Rated Working Volume (mass) Jacketed Tank	906 lbs (411 kg)
	Minimum Ceiling Height Recommended	10' (305 cm)

500 L Tank	Rated Liquid Working Volume	500 L
	Minimum Liquid Working Volume	100 L
	BPC Chamber Diameter	29.75" (75.6 cm)
	BPC Chamber Shoulder Height	57.5" (146 cm)
	Liquid Height @ Rated Working Volume	44" (111.8 cm)
	Overall Geometry (height/diameter ratio)	1.5:1
	Fluid Geometry @ Working Volume (height/diameter) Ratio	1.7:1
	Impeller (quantity x blade count)	1 x 3
	Impeller Diameter	7.875" (20 cm)
	Hold-Up Volume (typical)	<100 mL
	Skid Width	30.4" (77 cm)
	Skid Depth	37.4" (95 cm)
	Skid Height	65.1" (165.3 cm)
	Dry Skid Weight (mass) Non-Heated Tank	776 lbs (352 kg)
	Dry Skid Weight (mass) Jacketed Tank	802 lbs (364 kg)
	Wet Skid Weight—Rated Working Volume (mass) Non-Heated Tank	1878 lbs (852 kg)
	Wet Skid Weight—Rated Working Volume (mass) Jacketed Tank	1905 lbs (864 kg)
	Minimum Ceiling Height Recommended	11' (335 cm)
1000 L Tank	Rated Liquid Working Volume	1000 L
	Minimum Liquid Working Volume	200 L
	BPC Chamber Diameter	41.5" (105.4 cm)
	BPC Chamber Shoulder Height	61.9" (157.2 cm)
	Liquid Height @ Rated Working Volume	45.5" (115.6 cm)
	Overall Geometry (height/diameter ratio)	1.1:1
	Fluid Geometry @ Working Volume (height/diameter) Ratio	1.2:1
	Impeller (quantity x blade count)	1 x 3
	Impeller Diameter	7.875" (20 cm)
	Hold-Up Volume (typical)	<300 mL
	Skid Width	49.6" (126 cm)
	Skid Depth	49.3" (125.2 cm)
	Skid Height	63.4" (161 cm)
	Dry Skid Weight (mass) Non-Heated Tank	880 lbs (399 kg)
	Dry Skid Weight (mass) Jacketed Tank	913 lbs (414 kg)
	Wet Skid Weight—Rated Working Volume (mass) Non-Heated Tank	3084 lbs (1399 kg)
	Wet Skid Weight—Rated Working Volume (mass) Jacketed Tank	3117 lbs (1414 kg)
	Minimum Ceiling Height Recommended	11' (335 cm)

3.6.3 Docking Station Control Panel Layout



3.7 Recalibration of the AC-Tech Variable Speed Drive (SCF/SCM Models)

If during the verification of the mixer speed calibration it was determined the displayed speed varied from the actual speed, please follow these steps to recalibrate the drive:

1. Press “M” on the speed controller menu.
2. If “000” appear, the menu is locked. To unlock the menu, hold the up arrow key and select “225” then press the menu key.
3. Use the arrow key to select “P39” and then press “M”.
4. Use the arrow keys to enter the correct value listed in the Table 3.1, then press “M”. **NOTE:** The value may need to be adjusted +/- slightly to calibrate exactly.

S.U.M. VFD Parameters for RPM Calibration +/- 1 rpm			
S.U.M. Unit	Parameter	Value	Value derived from:
50, 200, 500, 1000, and 2000 L (SCF/SCM models)	P39	356	Motor rating of 1780 rpm (60 Hz) with gear reduction of 5:1 -- $1780/5:1 = 356$

Table 3.1. VFD Parameters

5. The mixer output should now be scaled properly for the correct RPM displayed.

NOTE: For users who currently operate the S.U.M. and have not previously verified the calibration of the system, the current calibration of the system should be verified so an approximate operating RPM for any previous S.U.M. runs can be documented and compared to the newly calibrated system. Users can then verify the parameters in the above table and change them if necessary. To confirm that the parameter change provides a calibration accuracy of +/- 1 RPM, conduct a final check of the calibration (see Section 2.1). p

3.8 Troubleshooting

Symptom	Single-Use Mixer will not operate.
Remedy	<p>Check power supply.</p> <ul style="list-style-type: none">• Verify main electrical plug connection at wall outlet, verify position of main power disconnect and verify position of Emergency Stop switch.• Verify condition of main electrical circuit breaker of facility. If protection breaker is tripped, determine fault condition. The condition may exist where other electrical systems are requiring current loads beyond those allowed by the breaker. S.U.M. system should be placed on its own electrical circuit.• Disconnect main power cord. Inspect electrical circuit breakers and fuses inside the electrical enclosure of the S.U.M. controller. Determine fault condition by visual inspection. If fault condition can not be determined by visual inspection, contact manufacturer.
Symptom	Speed controller does not respond to user inputs
Remedy	<p>Allow speed to stabilize before using keypad interface</p> <ul style="list-style-type: none">• Rapidly adjusting speed control in an excessive manner may require several seconds for speed stabilization.• Wait ten seconds and then attempt to adjust speed at keypad interface.
Symptom	There is too much tension in the film near the bearing port of the loaded BPC.
Remedy	<p>Reload the bag (if possible) by carefully following the instructions in this user's guide.</p> <ul style="list-style-type: none">• Provide excess film to that region of the BPC nearest the bearing port when aligning the bag in the tank.• Do not begin liquid fill until the bag is properly seated in the tank.• Verify the black bumper located in the motor mount block is present.

Symptom	I am not familiar with the use of the Pall Kleenpak Connectors and am concerned about making connections. What can I do to ensure a successful connection using this system?
Remedy	<p>Familiarize yourself with the Pall Kleenpak Connector instructions found in Section 2.5 before beginning.</p> <ul style="list-style-type: none">• When a connection is being made, visually evaluate the status of the four locking external clips and verify they are tightly secured (the snap should be audible for all four clips when pressing the connectors together). Always make sure the four locking clips are fully engaged for the male/female connection before removing the paper strips.• A common cause for a leaky Kleenpak is an error in the final step of seating the tapered barrels of the male/female connector. There are a series of concentric rings inside the male connector (0.3" in front of the black o-ring) Visually verify that the four internal clips are on the last set of rings. Using both hands place connector flanges between index fingers and thumbs and squeeze until properly seated.
Symptom	pH levels are questionable or out of range.
Remedy	<p>Verify calibration of probe, utilize either media or gas buffers.</p> <ul style="list-style-type: none">• pH levels can be managed in a similar manner to conventional once calibration of the probe is verified by use of an off-line sample. See Section 2.3 for Probe Assembly instructions for more information on probe calibration.
Symptom	We forgot to introduce the pH probe prior to liquid fill; can we still make a sterile connection under these conditions?
Remedy	<p>Yes, as long as the clamps were closed on the Kleenpak Connector probe ports before liquid fill.</p> <ul style="list-style-type: none">• The Kleenpak connectors must be dry to make the connection of the probe assemblies. When media is already present in the S.U.M., follow the probe insertion procedures as outlined in Section 2.3. Some fluid may enter the bellows when the probe is inserted into a BPC already filled with fluid.

Section 4 Ordering Information

This section covers the following:

- 4.1 Ordering Information: BPC Disposables**
- 4.2 Ordering Information: Hardware**
- 4.3 Ordering Information: Accessories**
- 4.4 Replacement and Spare Parts**
- 4.5 Ordering Instructions**
- 4.6 Ordering/Support Contact Information**

4.1 Ordering Information

BPC Disposables

Standard BPC Products

Part Number	Description
SH30768.01	50 L BPC for S.U.M. (gamma-sterilized), Powder to Liquid Mixing
SH30768.02	50 L BPC for S.U.M. (gamma-sterilized), Powder to Liquid Mixing with Probe Ports
SH30767.01	50 L BPC for S.U.M. (gamma-sterilized), Liquid to Liquid Mixing
SH30767.02	50 L BPC for S.U.M. (gamma-sterilized), Liquid to Liquid Mixing with Probe Ports
SH30762.04	50 L Liner for S.U.M. (gamma-sterilized), Open Top Mixing
SH30749.06	50 L Open Top Mixing Impeller Sleeve
SH30750.01	200 L BPC for S.U.M. (gamma-sterilized), Powder to Liquid Mixing
SH30750.02	200 L BPC for S.U.M. (gamma-sterilized), Powder to Liquid Mixing with Probe Ports
SH30753.01	200 L BPC for S.U.M. (gamma-sterilized), Liquid to Liquid Mixing
SH30753.02	200 L BPC for S.U.M. (gamma-sterilized), Liquid to Liquid Mixing with Probe Ports
SH30762.01	200 L Liner for S.U.M. (gamma-sterilized), Open Top Mixing
SH30749.08	200 L Open Top Mixing Impeller Sleeve
SH30751.01	500 L BPC for S.U.M. (gamma-sterilized), Powder to Liquid Mixing
SH30751.02	500 L BPC for S.U.M. (gamma-sterilized), Powder to Liquid Mixing with Probe Ports
SH30754.01	500 L BPC for S.U.M. (gamma-sterilized), Liquid to Liquid Mixing
SH30754.02	500 L BPC for S.U.M. (gamma-sterilized), Liquid to Liquid Mixing with Probe Ports
SH30762.02	500 L Liner for S.U.M. (gamma-sterilized), Open Top Mixing
SH30749.10	500 L Open Top Mixing Impeller Sleeve
SH30752.01	1000 L BPC for S.U.M. (gamma-sterilized), Powder to Liquid Mixing
SH30752.02	1000 L BPC for S.U.M. (gamma-sterilized), Powder to Liquid Mixing with Probe Ports
SH30755.01	1000 L BPC for S.U.M. (gamma-sterilized), Liquid to Liquid Mixing
SH30755.02	1000 L BPC for S.U.M. (gamma-sterilized), Liquid to Liquid Mixing with Probe Ports
SH30762.03	1000 L Liner for S.U.M. (gamma-sterilized), Open Top Mixing
SH30749.10	1000 L Open Top Mixing Impeller Sleeve (same as for 500 L S.U.M.)
SH30770.01	2000 L BPC for S.U.M. (gamma-sterilized), Powder to Liquid Mixing
SH30770.02	2000 L BPC for S.U.M. (gamma-sterilized), Powder to Liquid Mixing with Probe Ports
SH30769.01	2000 L BPC for S.U.M. (gamma-sterilized), Liquid to Liquid Mixing
SH30769.02	2000 L BPC for S.U.M. (gamma-sterilized), Liquid to Liquid Mixing with Probe Ports
SH30762.05	2000 L Liner for S.U.M. (gamma-sterilized), Open Top Mixing
SH30772.01	2000 L Open-Top Mixing Impeller Sleeve

NOTE: Not all options are available for all ports. Customization of port type and location, chamber dimensions or mixing assembly is **NOT** available. For additional information, please refer to the Selection Guides in the 2008 BPC Catalog.p

4.2 Ordering Information

Hardware

Standard Products

Non-Heated Part Number	Description
SV50212.01	50 L S.U.M., 120 VAC, Single Phase
SV50212.02	50 L S.U.M., 240 VAC, Single Phase
SV50213.01	200 L S.U.M., 120 VAC, Single Phase
SV50213.02	200 L S.U.M., 240 VAC, Single Phase
SV50214.01	500 L S.U.M., 120 VAC, Single Phase
SV50214.02	500 L S.U.M., 240 VAC, Single Phase
SV50215.01	1000 L S.U.M., 120 VAC, Single Phase
SV50215.02	1000 L S.U.M., 240 VAC, Single Phase
SV50216.01	2000 L S.U.M., 120 VAC, Single Phase
SV50216.02	2000 L S.U.M., 240 VAC, Single Phase
Water Jacket Part Number	Description
SV50212.03	50 L S.U.M., 120 VAC, Single Phase
SV50212.04	50 L S.U.M., 240 VAC, Single Phase
SV50213.03	200 L S.U.M., 120 VAC, Single Phase
SV50213.04	200 L S.U.M., 240 VAC, Single Phase
SV50214.03	500 L S.U.M., 120 VAC, Single Phase
SV50214.04	500 L S.U.M., 240 VAC, Single Phase
SV50215.03	1000 L S.U.M., 120 VAC, Single Phase
SV50215.04	1000 L S.U.M., 240 VAC, Single Phase
SV50216.03	2000 L S.U.M., 120 VAC, Single Phase
SV50216.04	2000 L S.U.M., 240 VAC, Single Phase

Custom BPC Products

Tubing Type	C-Flex (clear, white and ADCF), Silicone, PVC, PharMed or PharmaPure
Tubing Size	Specific Lengths of 1/8 to 1" (3.18 to 25.4 mm) ID - depending on type of tubing chosen
Connectors	Luer - 1/8 to 1/2" (3.18 to 12.7 mm) ID CPC - 1/4 to 3/4" (6.35 to 19 mm) ID SIP Connector - 1/4 to 3/4" (6.35 to 19 mm) ID Tri-clamp - 1/8" to 1" (3.18 - 25.4mm) ID Mini-Tri-clamp - 1/8 to 1/2" (6.35 to 12.7 mm) ID Aseptic Connection Device - All available sizes of Pall Kleenpak and BioQuate DAC
Others	Needle-free sample port (SmartSite or Clave) Filter Capsule (Millipore, Pall, Sartorius, Domnick Hunter, Meissner, Other

BPC Presentation

Outer Packaging	Supplied "flat-packed" in 2 outer layers of polyethylene.
Label	Description, product code, lot number and expiry data on outer packaging and shipping container.
Sterilization	By irradiation (25-38 kGy) inside outer packaging.
Shipping Container	Strong cardboard carton.
Documentation	A certificate of analysis is supplied with each lot for each delivery.

4.3 Ordering Information

Accessories

Part Number	Description	
SH30720.01	Probe Assembly (non-sterile)	Used to package probes (not supplied) for sterilization and to aseptically connect them to the S.U.M. BPC.
SV20664.01	Heavy Duty Tubing Clamp	Reusable tubing clamp used on probe ports when connecting probe assembly.
SV20664.02	Heavy Duty Tubing Clamp (4 pack of SV20664.01)	
SV20664.03	Heavy Duty Tubing Clamp (10 pack of SV20664.01)	
SV20750.01	S.U.M. thermo-well/sample port	Used for RTD calibration/validation.
SV20778.01	RTD	Pt100 Resistance Temperature Detector for use with S.U.M BPC thermo-well/sampling port.
SV50177.01	Autoclave Tray for Probe Kits (stainless steel)	Support tray which allows the probes to be safely autoclaved.
SH30845.01	Sterile Sampling Manifold with luer lock (individual)	Available for aseptic luer connection or welding onto the sample line to take sample sets.
SH30845.02	Sterile Sampling Manifold with luer lock (10 pack)	
SV50194*	Load Cells	Installed by manufacturer or end-user
SV50177.29	Probe Shelf for 50 L S.U.M.	Support shelf for use with probe assemblies.
SV50177.93	Probe Shelf for 200 L S.U.M.	Support shelf for use with probe assemblies.
SV50177.94	Probe Shelf for 500 L S.U.M.	Support shelf for use with probe assemblies.
SV50177.95	Probe Shelf for 1000 L S.U.M.	Support shelf for use with probe assemblies.
SV50177.96	Probe Shelf for 2000 L S.U.M.	Support shelf for use with probe assemblies.
SV50177.02	Probe Holder	For use with probe shelf
SV50177.249	Probe Holder	For use with hanging probes
SV50187.01	Powdertainer Hanger with Support Collar	To support Powdertainer and S.U.M. bag during connection (for S.U.M. sizes 50 L through 1000 L)
SV50187.03	Powdertainer Hanger with Support Collar	To support Powdertainer and S.U.M. bag during connection (for use with the 2000 L S.U.M.)
SV50187.05	Powdertainer Hanger with Dual Support Collars	To support Powdertainer and Bearing Port (for bag use in Docking Tanks)
SV50177.77	Reusable Bearing Port (quick connect)	For use with 50-1000 L S.U.M. systems
SV50177.78	Reusable Bearing Port (tri-clamp)	For use with 2000 L S.U.M. system

* For more information on Load Cell options refer to Data Sheet 048.

4.4 Replacement & Spare Parts

For a list of replacement parts and spare parts, please refer to the Single-Use Mixer Equipment Turnover Package.

4.5 Ordering Instructions

Disposable components for the S.U.M. can be ordered direct by contacting your Thermo Scientific HyClone products sales representative. These items include all components that have part numbers beginning with the following two digits:

- SH
- SV

Other components related to the hardware and outer support container of the S.U.M. can be ordered directly from the hardware manufacturer:

ConeCraft

2702B N. Nichols Street
Fort Worth, TX 76106
Tel: +1 (817) 625 7005
Fax: +1 (817) 625 8001

4.6 Ordering/Support Contact Information

In the Americas and Asia:

In Europe:

Tel: +1 (435) 792 8000

Tel: +32 53 85 75 59

Toll-free: +1 (800) HyClone

Fax: +32 53 85 74 31

Or +1 (800) 492 5663

perbio.euromarketing@thermofisher.com

Fax: +1 (435) 792 8001

www.thermo.com/perbio

www.thermo.com/hyclone

Info@hyclone.com

Technical Support

Technical support for the Single-Use Mixer is available through a variety of formats. Some or all of the following may be appropriate depending on individual experience and circumstances.

Contact your sales representative for general product pricing, availability, delivery, order information and product complaints.

Technical Service Hotline

Call 1-800-HyClone (US) or 32 53 85 75 59 (EU) for direct and immediate response to overall product questions and general product technical information (Technical Support). You can also contact our Tech Support by email at: hyc.bpctechsupport@thermofisher.com.

Initial Setup and Operation

Appropriate technical support is available to assist in the initial setup and operation of each Single-Use Mixer system. Inquire at the time of purchase.

Training

Training can be provided for startup and operation of the S.U.M. Contact your sales representative for Thermo Scientific HyClone products.



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